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Jc518 U.S. PTO
09/23/96
01/27/99

01/27/99
Jc408 U.S. PTO

BOX PATENT APPLICATION

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Atty Docket: C0136.HTM

Sir:

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For: Interface Device and Method for Interfacing Instruments to Medical
Procedure Simulation Systems

Enclosed are:

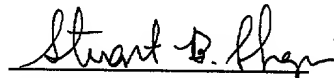
New Patent Application including:
Forty-one (41) pages of Specification; and

Fourteen (14) Sheets of Drawings;

All correspondence regarding this application should be directed to EPSTEIN, EDELL &

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Respectfully submitted,



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**INTERFACE DEVICE AND METHOD FOR INTERFACING INSTRUMENTS TO
MEDICAL PROCEDURE SIMULATION SYSTEMS**

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application Serial No. 08/923,477, filed September 4, 1997 and entitled "Interventional Radiology Interface Apparatus and Method", which claims priority from U.S. Provisional Patent Application Serial No. 60/025,433, filed September 4, 1996 and entitled "Interventional Radiology Interface Apparatus and Method". In addition, this application claims priority from U.S. Provisional Patent Application Serial No. 60/072,672, filed January 28, 1998 and entitled "Endoscopic Procedure Simulation System and Method"; from U.S. Provisional Patent Application Serial No. 60/105,661, filed October 26, 1998 and entitled "Endoscopic Surgical Simulation System and Method Including Pivotal Entry Site"; and U.S. Provisional Patent Application Serial No. 60/116,545, filed January 21, 1999 and entitled "Endovascular Procedure Simulation System and Method". The disclosures in the above-mentioned patent applications are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention pertains to computerized simulation systems, generally of the types disclosed in: International Publication Number WO 96/28800, published September 19, 1996 and entitled "Computer Based Medical Procedure Simulation System"; and the above-mentioned patent applications. The disclosure of the above-referenced international publication is incorporated herein by reference in its entirety. In particular, the present invention pertains to an interface device for a computerized medical procedure simulation system, the interface device including peripherals in the form of mock or actual medical instruments for use by a medical practitioner in performing various steps of a medical procedure in order to provide an enhanced realistic simulation of that procedure.

2. Discussion of Related Art

Generally, minimally invasive medical procedures, such as endoscopic or interventional radiological procedures, may be utilized by physicians to accomplish tasks that

1 would otherwise require a patient to undergo open surgery. For example, an angioplasty-
2 balloon procedure may be utilized by physicians to open and eliminate blockages in a blood
3 vessel, while endoscopic procedures may be utilized by physicians to view and/or perform
4 medical procedures on a bodily region of interest.

5 Performance of minimally invasive medical procedures, such as endoscopic or
6 interventional radiological procedures, requires great skill to avoid complications that may
7 cause serious injury to a patient and/or require the patient to undergo open surgery. For
8 example, in an angioplasty-balloon procedure, the physician is required to navigate a
9 guidewire, catheter and sheath through an arterial network to a blockage point and inflate a
10 balloon to eliminate the blockage, while avoiding a number of possible complications, such
11 as rupturing an artery wall or dissecting the wall of the artery. Thus, physicians need to
12 acquire the necessary skill levels and experience to perform minimally invasive medical
13 procedures in order to ensure successful performance of these types of procedures on patients.

14 Although practicing minimally invasive surgical procedures on live patients provides
15 excellent training, a procedure may usually only be performed once on a particular live
16 patient and typically requires the presence of a skilled physician to supervise and oversee the
17 procedure to avoid serious injury to the patient. Further, training physicians or other medical
18 professionals in minimally invasive surgical procedures on live patients requires the use of
19 proper facilities and equipment (e.g., hospital facilities and equipment), thereby incurring
20 substantial costs and limiting procedure practice to a particular time and location. Moreover,
21 since only one physician is able to practice a procedure on a particular live patient, the
22 quantity of physicians that may practice or perform minimally invasive surgical procedures is
23 severely restricted, thereby limiting the quantity of physicians that may acquire sufficient
24 experience to perform these types of procedures.

25 The prior art has attempted to overcome the above described disadvantages of
26 utilizing live patients to train physicians or other medical professionals to perform various
27 minimally invasive medical procedures by employing simulation techniques. In particular,
28 U.S. Patent No. 4,907,973 (Hon) discloses an expert system simulator for modeling realistic
29 internal environments. The simulator may be utilized to simulate an endoscopic procedure,
30 whereby a mock endoscope is inserted and manipulated within a model. The model includes
31 a mock bodily region of interest and a plurality of sensors to detect the position of the
32 endoscope. A computer receives signals from the sensors, and retrieves data from memory in

1 accordance with those signals representing the view observed from the measured endoscope
2 position during a real operation. The data is subsequently shown on a video display, whereby
3 the displayed image is adjusted based on movement of the endoscope within the model.
4 Alternatively, the simulator may be used to simulate an angioplasty-balloon operation,
5 whereby a mock catheter is inserted and manipulated within an internal arterial modeling
6 device. The internal arterial modeling device may include mock arterial paths with sensors to
7 track the progress of the inserted catheter within those paths. A computer retrieves and
8 processes data from storage based on sensor data received from the internal sensors, and
9 sends the processed data to a display that provides a visual display simulating a realistic
10 environment (e.g., a view of the catheter within an arterial network).

11 U.S. Patent No. 4,642,055 (Saliterman) discloses a hemodynamic monitoring training
12 system that allows medical professionals to obtain substantial experience in hemodynamic
13 monitoring (e.g., placement of a catheter passed from a distant vein through the heart to the
14 pulmonary vasculature for purposes of measuring intracardiac, pulmonary artery and wedge
15 pressures to determine the type or extent of cardiopulmonary disease, to evaluate therapeutic
16 measures and to monitor cardiac function). The system includes a trainer, computer, display,
17 keyboard and mouse and simulates the catheterization process. A catheter having a balloon
18 disposed at its distal end is inserted within a trainer manikin at a catheter insertion point. The
19 balloon is typically inflated to assist the catheter tip through the heart, and may be inflated in
20 the pulmonary artery to measure wedge pressure. The manikin includes tubes representing
21 veins extending internally from the insertion points, and a position sensor that measures
22 advancement of the catheter tip past the sensor. The sensor data enables the computer to
23 determine the location of the catheter tip within a corresponding actual human body based on
24 catheter manipulation within the trainer manikin. The computer receives signals from the
25 trainer and may provide on the display a simulated fluoroscope image showing simulated
26 movement of the catheter through the heart and vasculature.

27 The Hon and Saliterman systems suffer from several disadvantages. Specifically,
28 these systems utilize a physical model, thereby restricting training of a medical procedure to a
29 particular bodily region or arterial paths defined by that model. Further, use of physical
30 models degrades realism of the simulation and reduces the benefits of simulation training
31 since the models usually do not contain substantially the same complex anatomy as an actual
32 body, and permit a physician or other medical professional to become accustomed to

1 performing a procedure on the same model anatomy. Performance of the procedure on
2 another bodily region or through different arterial paths within the Hon and Saliterman
3 systems typically requires a new model or substantial modifications to an existing model,
4 thereby limiting flexibility of the systems and increasing system costs. Moreover, the
5 Saliterman system does not provide computer-controlled force feedback to an instrument,
6 thereby degrading realism of the simulation and reducing the benefits of simulation training.
7 In other words, the Saliterman system does not provide a computer simulated feel of forces
8 applied to an instrument during an actual medical procedure.

9 In order to overcome the disadvantages of utilizing physical models described above,
10 medical procedure simulation systems employ virtual reality technology to simulate
11 performance of a medical procedure on a virtual bodily region of interest. Various types of
12 interface devices are typically utilized by these systems to enable a user to interact with the
13 simulation system. In addition, the interface devices may provide force feedback to the user
14 to simulate the forces encountered during an actual medical procedure. For example,
15 International Publication Number WO 95/02233 (Jacobus et al) discloses a medical procedure
16 simulation system that utilizes virtual reality technology and force feedback to provide an
17 accurate simulation of endoscopic medical procedures. The system includes a display device,
18 sound device, graphics/image processing engine and storage module and programmable
19 tactile/force reflecting mechanisms (e.g., disposed within an interface device) that provide
20 force feedback to generate the "feel" of medical instruments and the interaction of the
21 instruments with an anatomical simulation. Force feedback is typically accomplished by a
22 tactile/force reflecting mechanism via a four axis device that imparts forces and torques to a
23 user's hands through a member representative of a medical instrument in response to
24 manipulation of that member. The forces and torques are applied to the user's hands based on
25 the position of the member in relation to characteristics of a geometric model of an organ or
26 virtual reality simulation of a medical procedure environment. The forces and torques are
27 typically generated by four servomotors that manipulate the member to provide a realistic feel
28 during simulation.

29 U.S. Patent No. 5,623,582 (Rosenberg) discloses a human/computer interface tool,
30 typically for use with virtual reality simulation systems. The interface tool preferably
31 interfaces a substantially cylindrical object, such as a shaft of a surgeon's tool, to a simulation
32 system computer such that the computer may generate signals to provide a virtual reality

1 simulation with force feedback applied to the object. The interface tool includes a gimbal
2 mechanism, having two degrees of freedom, coupled to a support, and preferably three
3 electromechanical transducers. The object, when engaged by the gimbal mechanism, may
4 move with three degrees of freedom within a spherical coordinate space, whereby each
5 transducer is associated with and senses a respective degree of freedom of motion of the
6 object. A fourth transducer may be utilized by the interface tool to measure rotation of the
7 object about an axis. Alternatively, the interface tool may accommodate catheter insertion
8 virtual reality systems, typically utilizing catheters having two degrees of freedom of motion,
9 whereby the interface tool includes two transducers that are associated with and sense
10 translation and rotation of a catheter, respectively. The transducers of the interface tool may
11 include actuators to impart a force upon the object to provide force feedback to a user.

12 U.S. Patent No. 5,821,920 (Rosenberg et al) discloses an apparatus for interfacing an
13 elongated flexible object with an electrical system including an object receiving portion and a
14 rotation transducer. The rotation transducer determines rotational motion of an elongated
15 object when the object is engaged with the object receiving portion and provides an
16 electrochemical interface between the object and electrical system. The rotation transducer
17 may further include an actuator and translational transducer to further provide a translation
18 electrochemical interface between the object and electrical system. A tandem configuration
19 may be utilized for accommodating a device having an external shaft and an elongated
20 flexible object. This configuration includes first and second object receiving portions that
21 respectively accommodate the external shaft and elongated object. The first and second
22 object receiving portions each have an actuator and translation transducer, whereby a rotation
23 transducer is rotatably coupled to the second object receiving portion. In another
24 embodiment, an object receiving portion may be part of a gimbal apparatus. The transducers
25 of the interface device may be implemented as input transducers for sensing motion, or output
26 transducers for imparting forces onto the elongated object.

27 U.S. Patent No. 5,704,791 (Gillio) discloses a virtual surgery system that enables
28 simulation of a surgical procedure using image data of a patient and devices simulating the
29 physical instruments a surgeon utilizes in an actual procedure. Image data, corresponding to a
30 portion of an anatomy in a three dimensional data set, is stored in a memory of a computer,
31 whereby a user input device is used to move through the image data, while the image data is
32 viewed on a display. A virtual surgery may be simulated based on the image data and

manipulation of the input device. Further, force feedback may be provided based on physical constraint models or edge and collision detection between a virtual tool and walls or edges of the image data. Moreover, the virtual simulator may be utilized to record data of an actual surgical procedure, or as a remote telesurgery device. In addition, a surgical simulator user input device of the system includes a first virtual scope device attached to an end-portion of a hose that extends into and through a first virtual orifice and a box device. The first virtual orifice is attached at a top portion of the box device and accommodates the hose, while the box device includes an arrangement that handles and may further apply force feedback to the hose. A second instrument is attached to a shaft that extends through a second virtual orifice defined in the first virtual scope device. Signals from the first virtual scope device, the second instrument and/or the first and second virtual orifices are provided to the computer to enable simulation of a surgical procedure.

The virtual reality systems described above suffer from several disadvantages. In particular, the virtual reality systems generally interface an elongated object without utilizing mechanisms to firmly grasp and capture the object, thereby degrading accuracy of object motion measurements. Further, the virtual reality systems generally accommodate a limited quantity of instruments within a nested instrument assembly, and do not permit exchange of instruments during a simulation, thereby reducing the benefits of simulation training since a medical professional may only gain experience for portions of a medical procedure utilizing the accommodated instruments. Similarly, the virtual reality systems generally accommodate either a limited quantity of independently inserted instruments, or a single nested instrument assembly, thereby limiting simulation training to specific procedures or portions of procedures utilizing the accommodated instruments (e.g., the systems generally do not accommodate plural independently inserted nested instrument assemblies, or plural independently inserted instruments where one of the instruments is a nested instrument assembly). Moreover, the virtual reality systems typically include fixed entry sites, thereby limiting the simulated procedure to a particular patient or entry site orientation. In addition, the Jacobus and Rosenberg (U.S. Patent No. 5,623,582) systems generally employ a plurality of actuators to provide force feedback to a single instrument, thereby increasing system complexity and cost.

Another computer interface device for surgical simulation systems includes the Immersion PROBE produced by Immersion Corporation of Palo Alto, California. This

1 interface device includes a pen-like stylus supported on a light-weight mechanical linkage
2 having six degrees of freedom, and reports the position and orientation of the stylus to a
3 computer via a serial port interface. Sensors are disposed at the linkage joints and send
4 spatial coordinates (i.e., X, Y, Z) and orientation (i.e., roll, pitch, yaw) of the stylus to the
5 computer. However, this interface device does not resemble a common medical instrument
6 and does not provide a manner to apply computer controlled force feedback to the interface
7 device, thereby degrading realism of a simulation and reducing benefits of simulation
8 training.

9 **OBJECTS AND SUMMARY OF THE INVENTION**

10 Accordingly, it is an object of the present invention to enhance realism within a
11 medical procedure simulation system by interfacing various peripherals in the form of mock
12 medical instruments to the medical procedure simulation system via an interface device to
13 enable realistic simulation of various aspects of a medical procedure.

14 It is another object of the present invention to provide enhanced training of a medical
15 procedure to medical practitioners by permitting exchanges of various medical instruments
16 during a simulated medical procedure to enable the medical practitioner to simulate
17 performance of a substantial portion of a medical procedure.

18 Yet another object of the present invention is to enhance realism within a medical
19 procedure simulation system and to provide enhanced training of a medical procedure to
20 practitioners by interfacing plural independently inserted instruments (e.g., that may include a
21 nested instrument assembly) to the medical procedure simulation system via an interface
22 device to enable realistic simulation of these instruments during a medical procedure.

23 Still another object of the present invention is to enhance measurement of instrument
24 motion within the interface device by firmly grasping and capturing an instrument via an
25 interface device capture mechanism.

26 A further object of the present invention is to enhance realism within a medical
27 procedure simulation system and to provide enhanced training of a medical procedure to
28 medical practitioners by enabling a patient entry site to be manipulable to various orientations
29 to permit realistic simulation of medical procedures on patients in different positions.

30 The aforesaid objects are achieved individually and in combination, and it is not
31 intended that the present invention be construed as requiring two or more of the objects to be
32 combined unless expressly required by the claims attached hereto.

1 According to the present invention, an interface device and method for interfacing
2 instruments to a medical procedure simulation system, typically including a computer system
3 and display, serve to interface peripherals in the form of mock medical instruments to the
4 medical procedure simulation system computer to enable simulation of medical procedures.
5 The interface device includes a housing having a mock bodily region of interest to facilitate
6 insertion of a mock instrument, such as an endoscope tube, into the interface device via an
7 orifice. The mock bodily region of interest may be pivotable to simulate various patient
8 orientations. The endoscope tube traverses the orifice and a guide tube, and is subsequently
9 engaged by a capture mechanism in order to measure rotational and translational motion of
10 the endoscope tube. The capture mechanism is disposed at the proximal end of an inner tube,
11 disposed in slidable relation within an outer tube, whereby the outer tube receives the
12 endoscope tube from the guide tube. The inner tube distal end is attached to a trolley
13 assembly having a rotational encoder to measure rotation of the inner tube, and hence, the
14 endoscope tube, whereby the trolley assembly is coupled to a belt extending between and
15 about first and second pulleys. A translational encoder is disposed proximate the first pulley
16 to measure pulley rotation based on belt or trolley assembly motion, thereby providing an
17 indication of endoscope tube translational motion. An actuator is disposed proximate the
18 second pulley to impede or enhance pulley rotation and belt or trolley assembly motion,
19 thereby providing force feedback to the endoscope tube. The measured motion is provided to
20 the computer system to reflect instrument motion on the display during the simulation.

21 Alternatively, the interface device may be configured to measure instrument
22 manipulation via a carrier assembly. The instrument is inserted into the interface device, and
23 extends to the carrier assembly. The carrier assembly includes a rotational encoder having a
24 rotatable shaft that engages the instrument, via a set screw, to measure rotational motion. The
25 carrier assembly is attached to a belt that extends between and about first and second pulleys.
26 A translational encoder is disposed proximate the first pulley to measure pulley rotation
27 based on carrier assembly motion, thereby providing an indication of instrument translational
28 motion. An actuator is disposed proximate the second pulley to impede pulley rotation and
29 belt or carrier assembly motion, thereby providing force feedback to the instrument.

30 The interface device may further be configured to measure instrument manipulation
31 via a carriage assembly. The instrument is inserted into the interface device and extends
32 through a bellows to the carriage assembly. The bellows includes a series of stabilizer

1 openings to prevent buckling of the instrument. The carriage assembly includes a capture
2 mechanism in the form of a collet assembly to grasp the instrument, and a rotational encoder
3 to measure rotational motion of the instrument. A translational encoder is disposed toward
4 the carriage assembly upper portion proximate an encoder strip to measure translational
5 motion of the carriage assembly, and hence, the instrument translational motion. The carriage
6 assembly is connected to a belt extending between and about first and second pulleys. An
7 actuator is disposed proximate the first pulley to enhance or impede pulley rotation and
8 carriage assembly motion, thereby providing force feedback to the instrument. This
9 configuration may further include a plurality of carriage assemblies to accommodate
10 instrument assemblies having a plurality of nested instruments, whereby each carriage
11 assembly includes a collet assembly of a particular dimension and grasps, measures
12 manipulation of and provides force feedback to a particular instrument as described above. In
13 addition, the interface device may include a plurality of the carriage assembly configurations
14 described above arranged in parallel relation to simultaneously accommodate a plurality of
15 independently inserted instruments.

16 The above and still further objects, features and advantages of the present invention
17 will become apparent upon consideration of the following detailed description of specific
18 embodiments thereof, particularly when taken in conjunction with the accompanying
19 drawings wherein like reference numerals in the various figures are utilized to designate like
20 components.

21 **BRIEF DESCRIPTION OF THE DRAWINGS**

22
23 Fig. 1 is a block diagram of a medical procedure simulation system including an
24 interface device according to the present invention.

25 Fig. 2 is a schematic illustration of an exemplary display for the medical procedure
26 simulation system of Fig. 1.

27 Fig. 3 is a side view in elevation and partial section of the interface device of the
28 medical procedure simulation system of Fig. 1.

29 Fig. 4 is a side view in elevation and partial section of an instrument capture
30 mechanism of the interface device of Fig. 3.

31 Fig. 5 is a side view in elevation and partial section of the instrument capture
32 mechanism of Fig. 4 in an expanded state to receive or release an endoscope navigation tube.

1 Fig. 6 is a side view in elevation and partial section of the instrument capture
2 mechanism of Fig. 4 in a compressed state to engage an endoscope navigation tube.

3 Fig. 7 is a side view in elevation and partial section of a medical procedure simulation
4 system interface device including a pivotable entry site according to the present invention.

5 Fig. 8 is a view in elevation of an interface device motion communication tube including
6 an instrument capture mechanism according to the present invention.

7 Fig. 9 is a block diagram of the medical procedure simulation system of Fig. 1 having
8 an interface device accommodating a wire, catheter and sheath according to the present
9 invention.

10 Fig. 10 is a side view in elevation of an exemplary wire, catheter and sheath assembly.

11 Fig. 11a is a side view in elevation and partial section of an interface device for
12 interfacing a catheter to a medical procedure simulation system according to the present
13 invention.

14 Fig. 11b is a side view in elevation and partial section of a carrier of the interface
15 device of Fig. 11a.

16 Fig. 12 is an exploded view in perspective of an alternative embodiment of the
17 interface device of Fig. 11a according to the present invention.

18 Fig. 13a is an exploded perspective view of a carriage assembly of the interface device
19 of Fig. 12.

20 Fig. 13b is a perspective view of a collet of the carriage assembly of Fig. 13a.

21 Figs. 14a-14d are side views in elevation and partial section of the carriage assembly
22 of the interface device of Fig. 12 illustrating operation of an instrument capture and quick-
23 release mechanism.

24 Fig. 15 is an exploded view in perspective of an alternative embodiment of the
25 interface device of Fig. 12 accommodating plural independently inserted instruments
26 according to the present invention.

27 Fig. 16 is a side view in elevation and partial section of an interface device
28 configuration of the device of Fig. 15 including plural carriage assemblies for accommodating
29 a wire, catheter and sheath assembly according to the present invention.

30 Figs. 17a-17b are a side views in elevation and partial section of an interface device
31 configuration of the interface device of Fig. 15 including plural carriage assemblies having an
32 automatic capture and release mechanism according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

An overall system for simulating medical procedures, preferably endoscopic procedures such as bronchoscopy, laryngoscopy, gastroscopy, colonoscopy, sigmoidoscopy, arthroscopy, laparoscopy or ureteroscopy, is illustrated in Fig. 1. Specifically, the medical procedure simulation system includes a computer system 25, an interface device 20, an actual or mock endoscope 22 and a communications interface 24 for transferring signals between computer system 25, interface device 20 and actual or mock endoscope 22. Computer system 25 preferably includes a monitor 28, base 26 (e.g., including processor(s), memories and accompanying hardware), keyboard 27 and mouse 29, and is typically implemented by a conventional or commercially available workstation, such as those manufactured by IBM, Dell or Silicon Graphics, Inc. The computer system simulates, via software, an endoscopic or other medical procedure (e.g., an interventional radiology procedure), while displaying a simulated particular bodily region of interest (e.g., a tracheobronchial tree having a plurality of segments) on monitor 28. The simulation display preferably emulates an endoscopic video display of an image retrieved by a fiber-optic camera system integrated into an endoscope. An exemplary display of the simulation system showing a tracheobronchial tree is illustrated in Fig. 2.

Interface device 20 includes at least one orifice, such as a simulated nostril, throat, anus, or puncture (as by trocar) etc., for receiving actual or mock endoscope 22. Endoscope 22 typically includes a handle 21, working channel 15, working channel tool 23, thumb lever 19 and switches 18. The endoscope is typically inserted into an interface device orifice and manipulated to perform a simulated endoscopic procedure. Interface device 20 measures manipulation of endoscope 22 and working channel tool 23, and provides signals indicating the measured manipulation to computer system 25. Computer system 25 processes the signals to display, via monitor 28, the internal bodily region of interest (e.g., a tracheobronchial tree as shown in Fig. 2), while adjusting the display to reflect manipulation of endoscope 22 (e.g., including manipulation of switches 18 and thumb lever 19) and working channel tool 23. Computer system 25 further provides force feedback to the endoscope based on manipulation of the endoscope. Communications interface 24 transfers the manipulation and force feedback signals between computer system 25, interface device 20 and endoscope 22.

Working channel tool 23 enables simulation of various devices, such as a needle transbronchial biopsy tool, a grasping bronchial biopsy tool, forceps, laser or other instrument that may be inserted within and manipulated via an endoscope working channel during an endoscopic procedure. The working channel tool is similar to a cable attached to an actual biopsy tool, forceps or transbronchial biopsy tool. A mock endoscope for the simulation system typically contains approximately ten inches of the working channel tool and permits the working channel tool to move within and external of the endoscope approximately three inches, or to be removed entirely and replaced by a different working channel tool. Translational and rotational motion of the working channel tool is generally measured by encoders (not shown) disposed within the endoscope. The working channel may optionally include actuators to provide force feedback to the working channel tools.

An exemplary interface device 20 for the endoscopic procedure simulation system is illustrated in Fig. 3. Specifically, interface device 20 typically includes a mock bodily region of interest having an orifice for receiving an endoscope. By way of example only, the interface device includes a mock head 62 having a nostril 36 for receiving an endoscope 22, typically a bronchoscope. Endoscope 22 includes a navigation tube 49 that is inserted within nostril 36. A guide tube 34 is disposed adjacent nostril 36. The guide tube includes cross-sectional dimensions greater than the cross-sectional dimensions of navigation tube 49 such that the navigation tube extends through guide tube 34 to interface an instrument capture mechanism 38. Guide tube 34 extends from nostril 36 and curves approximately ninety degrees to interface an outer tube 58. Outer tube 58 includes cross-sectional dimensions greater than the cross-sectional dimensions of guide tube 34 such that a step or shoulder 104 is formed at the interface between the outer and guide tubes. An inner tube 56 includes cross-sectional dimensions less than the cross-sectional dimensions of outer tube 58, whereby the inner tube is disposed in slidable relation within the outer tube.

Capture mechanism 38 is disposed toward the proximal end of inner tube 56 and engages navigation tube 49 such that inner tube 56 is translated and rotated based on manipulation of endoscope 22 as illustrated in Fig. 4. Specifically, capture mechanism 38 is disposed toward the proximal end of inner tube 56 and includes disc 72, woven mesh tubular member 74 and substantially annular washers 68, 76, 78. Disc 72 is disposed at the capture mechanism distal end and is attached to washer 68 via fasteners 64, whereby the washer is disposed proximally of the disc. The distal end of woven mesh tubular member 74 is inserted

1 through washer 68 and attached to disc 72. The woven mesh tubular member is typically
2 constructed of spirally wound material and includes expandable and compressed states,
3 whereby the woven mesh tubular member cross-sectional dimensions increase when the
4 member is compressed and decrease when the member is expanded. The proximal end of
5 woven mesh tubular member 74 is inserted through washer 78 and attached to washer 76.
6 Washer 76 is disposed proximally of washer 78 and is connected to washer 78 via fasteners
7 64. A helical spring 70 is disposed between washers 68, 78 and about woven mesh tubular
8 member 74. The cross-sectional dimensions of the spring are greater than the cross-sectional
9 dimensions of the woven mesh tubular member and openings within washers 68, 78 to permit
10 the spring to enter expanded and compressed states. The spring enables the woven mesh
11 tubular member to enter the compressed and or expanded state in order to vary the tubular
12 member cross-sectional dimensions for engaging and releasing navigation tube 49. In
13 particular, expansion of spring 70 causes woven mesh tubular member 74 to expand, thereby
14 extending the woven mesh tubular member and decreasing the cross-sectional dimensions of
15 that member due to the spiral-shaped nature of the woven mesh material. Conversely,
16 compression of spring 70 decreases the length of woven mesh tubular member 74, thereby
17 increasing the cross-sectional dimensions of the woven mesh tubular member.

18 The differing cross-sectional dimensions of the woven mesh tubular member enable
19 capture mechanism 38 to securely grasp and release navigation tube 49 without electronic or
20 other mechanical mechanisms as illustrated in Figs. 5 - 6. Initially, inner tube 56 is disposed
21 within outer tube 58 with washer 76 positioned adjacent shoulder 104 of outer tube 58 (Fig.
22 5). Magnets 96, 98 (Fig. 3) are respectively disposed toward the distal ends of the inner and
23 outer tubes to maintain inner tube 56 within outer tube 58 and bias spring 70 to a compressed
24 state. The compressed state of spring 70 causes woven mesh tubular member 74 to enter a
25 compressed state, thereby increasing the woven mesh tubular member cross-sectional
26 dimensions. Navigation tube 49 is inserted into interface device 20 (Fig. 3) through guide
27 tube 34, whereby the increased cross-sectional dimensions of woven mesh tubular member
28 74 exceeds the cross-sectional dimensions of the navigation tube to permit the navigation
29 tube to enter the capture mechanism. Navigation tube 49 extends through woven mesh
30 tubular member 74 and interfaces disc 72. Additional force applied to the endoscope enables
31 navigation tube 49 to overcome the attraction force of magnets 96, 98 and to move inner tube
32 56 distally relative to outer tube 58 (Fig. 6). The motion of inner tube 56 enables spring 70 to

1 expand, thereby causing woven mesh tubular member 74 to enter an expanded state with
2 decreased cross-sectional dimensions. The decreased cross-sectional dimensions of the
3 woven mesh tubular member securely grip navigation tube 49 to enable inner tube 56 to be
4 manipulated based on forces applied to endoscope 22.

5 When navigation tube 49 is removed from interface device 20, inner tube 56 is moved
6 proximally within outer tube 58 to the state where washer 76 contacts shoulder 104 then
7 causing washer 68 to oppose the force of spring 70. The spring subsequently transitions from
8 an expanded (Fig. 6) to a compressed state (Fig. 5) as described above. The compression of
9 spring 70 causes woven mesh tubular member 74 to enter a compressed state, thereby
10 increasing the cross-sectional dimensions of the woven mesh tubular member. The attraction
11 force of magnets 96, 98 maintain inner tube 56 within outer tube 58, thereby maintaining the
12 compressed state of spring 70 and woven mesh tubular member 74. The increased cross-
13 sectional dimensions of woven mesh tubular member 74 exceeds the cross-sectional
14 dimensions of navigation tube 49, thereby enabling the woven mesh tubular member to
15 release the navigation tube to permit removal of the navigation tube from the interface device.

16 Referring back to Fig. 3, the distal end of inner tube 56 is connected to a trolley
17 assembly 46 that enables measurement of translational and rotational motion of navigation
18 tube 49 via sensed motion of inner tube 56. Trolley assembly 46 is attached to a belt 44 that
19 extends between and about a pair of pulleys 42, 43 disposed on corresponding supports 39,
20 41. Supports 39, 41 are separated by a distance similar to the length of inner tube 56, and
21 include guide rails 40 extending between the supports with belt 44 disposed between the
22 guide rails. Trolley assembly 46 includes openings defined in the trolley assembly portion
23 adjacent belt 44 for receiving guide rails 40 to direct trolley assembly motion. A rotation
24 encoder 30 is disposed on the trolley assembly and includes a shaft that interfaces the distal
25 end of inner tube 56 to measure rotational motion of navigation tube 49, while a translation
26 encoder 31 is disposed on support 41 to interface pulley 43 and measure translational motion
27 of the navigation tube. In particular, once navigation tube 49 interfaces capture mechanism
28 38, additional translational force applied to the endoscope (e.g., motion of the navigation
29 tube into simulated lungs) enables inner tube 56 to slide relative to outer tube 58, thereby
30 causing trolley assembly 46 to move along guide rails 40. The trolley assembly motion
31 manipulates belt 44 about pulleys 42, 43, thereby causing the pulleys to rotate. Rotation of
32 pulley 43 is measured by translation encoder 31 to provide an indication of translational

1 motion of the navigation tube into or out of the lungs, stomach, colon, etc. Further, rotational
2 motion of navigation tube 49 causes inner tube 56 to rotate, thereby enabling rotation encoder
3 30 to measure the navigation tube rotation. The capture mechanism secures navigation tube
4 49 to inner tube 56 such that rotation of the navigation tube causes rotation of inner tube 56.
5 Rotation and translation encoders 30, 31 essentially generate signals that are sent to
6 communications interface 24 (Fig. 1). The communications interface includes a processor or
7 other circuitry to determine respective encoder pulse counts and provide signals to computer
8 system 25 indicating rotational and translational motion of the navigation tube. Computer
9 system 25 processes the pulse counts to enable simulation of navigation tube rotation and
10 translation.

11 During an actual procedure, a medical practitioner is able to view the inside lumen or
12 other interior region of the bodily cavity. For example, a bronchoscope may be inserted into a
13 nasal opening and extend into the lungs. A medical practitioner typically manipulates the
14 bronchoscope in its degrees of freedom (e.g., translational, rotation and flexion of the
15 bronchoscope distal tip) to safely navigate down a lumen or opening in branches of a
16 bronchial tree. However, during navigation, the bronchoscope typically encounters
17 bifurcations (e.g., the bronchial tree bifurcates into various lobes, segments and sub-
18 segments) and may contact walls of the bronchi, whereby the medical practitioner feels forces
19 on the bronchoscope. This generally occurs when the medical practitioner fails to steer down
20 the center of one of the paths of the lung bifurcations, thereby contacting the bronchial wall at
21 the bifurcation. In order to simulate those or other forces encountered during an actual
22 procedure, a force feedback unit 60 is employed within the interface device. Specifically,
23 force feedback unit 60 is disposed on support 39 adjacent pulley 42 to impart forces
24 encountered during an actual procedure, such as touching lung walls or bronchial walls at a
25 bifurcation during a bronchoscope examination. Force feedback unit 60 is typically
26 implemented by an electromagnetic device and receives control signals from computer system
27 25 via communications interface 24. Computer system 25 determines, based on manipulation
28 of the endoscope, the feedback force to apply, and sends control signals to communications
29 interface 24. The communications interface includes digital to analog converters (DAC) and
30 converts the computer system control signals to analog signals in order to transmit the signals
31 to the interface device to control force feedback unit 60. The force feedback unit imparts a
32 magnetic force on pulley 42 to impede or enhance pulley rotation and trolley assembly

1 motion. The impeded motion requires additional force to be applied to the endoscope to
2 overcome the magnetic force, while enhanced motion requires application of less force,
3 thereby providing a realistic feel to the endoscopic procedure.

4 In addition, thumb lever 19 of endoscope 22 may be utilized to simulate flexing or
5 bending of the navigation tube distal end. Specifically, the endoscope typically includes an
6 encoder (not shown) to measure manipulation of thumb lever 19 and provide a signal to
7 computer system 25, via communications interface 24, in substantially the same manner
8 described above for the rotation and translation encoders. Manipulation of the thumb lever
9 enables simulation of virtual camera motion at the distal end of the endoscope. The thumb
10 lever may optionally include adjustable frictional resistance using any one of a number of
11 damping mechanisms, and additionally may include computer controlled force feedback via
12 an actuator (not shown). Switches 18 of endoscope 22 may be used to simulate irrigation
13 with fluids, suction of the fluids from the lungs and to control a simulated recording system
14 that may capture video and/or still images from the monitor system. The switches provide
15 signals to computer system 25, via communications interface 24, to enable the computer
16 system to perform the desired simulation.

17 Operation of the medical procedure simulation system to simulate an endoscopic
18 procedure is described, by way of example only, with reference to Figs. 1 and 3. Specifically,
19 a medical practitioner or user manipulates an endoscope 22, such as a bronchoscope, and
20 inserts navigation tube 49 into a bodily opening or nostril 36 of mock head 62. The
21 endoscope is typically manipulated in a manner similar to that utilized during an actual
22 procedure. Generally, the endoscope is held in one hand, while the other hand manipulates
23 the navigation tube. Navigation tube 49 traverses guide tube 34 and interfaces capture
24 mechanism 38. The capture mechanism engages navigation tube 49 as described above.
25 Once navigation tube 49 engages the capture mechanism, inner tube 56 and navigation tube
26 49 are effectively mated such that translational and rotational motion of the distal tip of
27 navigation tube 49 within the virtual patient is reflected by inner tube 56.

28 The translational and rotational motion of inner tube 56, and hence, navigation tube
29 49, is measured to enable computer system 25 to simulate the movement of the endoscope
30 within a virtual patient (e.g., the distance the navigation tube has been inserted into the virtual
31 patient and rotation of the navigation tube). As navigation tube 49 is inserted into or
32 withdrawn from interface device 20, the navigation tube applies force to inner tube 56 via

capture mechanism 38. The inner tube translational motion moves trolley assembly 46 between supports 39, 41, thereby causing belt 44 to rotate pulleys 42, 43. Translation encoder 31 attached to pulley 43 measures pulley rotation and provides a signal to computer system 25, via communications interface 24, indicating translational motion of the navigation tube. Rotational motion of the navigation tube causes inner tube 56 to rotate via capture mechanism 38. Inner tube 56 is coupled to rotation encoder 30 disposed on trolley assembly 46 such that the rotation encoder measures rotational motion of the inner tube. The rotation encoder provides a signal to computer system 25, via communications interface 24, indicating the rotational motion of navigation tube 49. In addition, force feedback unit 60, coupled to pulley 42, may be energized to provide force feedback to the endoscope when computer system 25 determines that the navigation tube has encountered an obstacle, such as a lung wall. The force feedback unit applies magnetic forces to impede or enhance rotation of pulley 42, and hence, motion of the belt and trolley assembly, thereby respectively requiring additional or less force to be applied to manipulate the navigation tube and imparting a realistic feel to the simulation.

Simulation of flexing the distal end of navigation tube 49 is accomplished via manipulation of thumb lever 19 of endoscope 22. The motion of the thumb lever is measured by an encoder (not shown), typically disposed within endoscope handle 21, that provides a signal to computer system 25, via communications interface 24, indicating the motion of the thumb lever. Computer system 25 processes the signal to determine flexing of the tube and a resulting simulated image produced from a camera based on the position of the flexed tube.

Once the endoscope is placed within the lungs of the simulated patient as described above and viewed on monitor 28, the medical practitioner may perform a simulated biopsy. The biopsy is typically performed by an assistant upon verbal command during an actual procedure, however, the simulated biopsy is performed by computer system 25 as described below. Initially, a biopsy tool is selected, via computer system 25, and working channel tool 23 is inserted into the endoscope and manipulated by the user to perform the biopsy. As working channel tool 23 is extended into the working channel of endoscope handle 21, computer system 25 displays simulated extension of the biopsy tool from the endoscope working channel (e.g., up to several centimeters beyond the distal end of the navigation tube).

The working channel tool is typically shown in the simulated visual field of the simulated fiber-optic camera. The medical practitioner continues to manipulate the working channel

1 tool to position the tool adjacent lung tissue of the simulated patient. Once the tool is
2 positioned, the medical practitioner commands computer system 25, via keyboard 27, to take
3 a sample. Computer system 25 proceeds to open and close biopsy forceps to simulate taking
4 of a biopsy from lung tissue. Thus, the simulated procedure is similar to an actual procedure
5 whereby an endoscope with a fiber optic camera at its distal tip is simulated by computer
6 system 25 based on manipulation of endoscope 22 within interface device 20.

7 The interface device may further be configured to include pivoting mechanisms to pivot
8 a mock bodily region of interest, such as a head, to various positions and/or orientations as
9 illustrated in Fig. 7. Interface device 120 is substantially similar to interface device 20 described
10 above, except that interface device 120 includes mechanisms to enable the mock bodily region
11 of interest to pivot. Interface device 120 measures manipulation of and provides force-feedback
12 to an instrument, such as endoscopic navigation tube 49 (Fig. 1) inserted within the interface
13 device during simulation of a medical procedure in substantially the same manner described
14 above. Specifically, interface device 120 includes a housing or case 122, a mock anatomical site
15 162, such as a head, an angle bracket or support 116 for supporting head 162 and pivoting
16 mechanisms 112, 114 for enabling head 162 to pivot relative to housing 122 and support 116,
17 respectively. Housing 122 includes front, rear and side walls that collectively define a housing
18 interior. The interface device front wall is typically formed of overlapping sections, such as an
19 upper section or overhang 152 and a lower section or flange 154. Sensing and force-feedback
20 assembly 110 is disposed within housing 122 for measuring manipulation of and providing force-
21 feed-back to endoscope navigation tube 49 during simulation of a medical procedure. The
22 sensing assembly includes substantially the same components and functions in substantially the
23 same manner as the interface device components described above to measure navigation tube
24 manipulation and provide force-feedback. Mock head 162 includes a nostril or orifice 136 that
25 serves as an entry site for receiving the endoscope navigation tube.

26 Angle bracket 116 is attached to lower section or flange 154 of the interface device front
27 wall. The angle bracket includes an interface section 170 that is attached, via pivoting
28 mechanism 112, to the interface device front wall, an anatomical site section 172 that supports
29 head 162, and an angled section 174 that extends between the interface and anatomical site
30 sections at an angle relative to each of those sections. However, the angle bracket sections may
31 be connected at any desired angle. Mock head 162 is affixed to a backing plate 118 via fasteners
32 126. Plate 118 is attached to pivoting mechanism 114 to enable head 162 to pivot relative to

1 angle bracket 116. Specifically, pivoting mechanism 114 includes a ring 130 rotatably coupled
2 to a fixed, substantially conical retainer 128. The ring is coupled to backing plate 118 by
3 fasteners 129 and is retained by conical retainer 128, which is in turn affixed to angle bracket 116
4 via fasteners 132. The ring may include any conventional pivoting and/or locking arrangements,
5 but preferably includes a spring-loaded ball bearing for interfacing detents defined in the ring
6 surface to enable the plate and ring to rotate and place head 162 in various positions and
7 orientations relative to the angle bracket.

8 Pivoting mechanism 112 is disposed between angle bracket 116 and the interface device
9 front wall. Pivoting mechanism 112 provides an additional degree of freedom for mock head 162
10 substantially orthogonal to the degree of freedom provided by pivoting mechanism 114. Pivoting
11 mechanism 112 includes a ring 134 that is rotatably coupled to a fixed, substantially annular
12 retainer 144 and attached to angle bracket 116 via fasteners 140. The retainer is attached to the
13 lower section or flange 154 of housing front wall via fasteners 142. Ring 134 is substantially
14 similar to ring 130 of pivoting mechanism 114, and enables the angle bracket to pivot relative
15 to housing 122. Ring 134 may include any conventional pivoting mechanisms, but preferably
16 includes a spring-loaded ball bearing for interfacing detents defined in the ring surface to enable
17 the angle bracket to rotate and place head 162 at various positions and orientations relative to
18 housing 122. In addition, a further locking mechanism (not shown) utilizing pressure and/or
19 frictional forces to prevent rotation via ring 134 may be employed to maintain head 162 at a
20 particular orientation relative to housing 122.

21 An outer tube 158 extends from nostril 136 through pivoting mechanism 114 (e.g.,
22 retainer 128 and ring 130) and angle bracket 116 and curves toward pivoting mechanism 112
23 disposed on flange 154 of interface device front wall. Outer tube 158 extends from the curved
24 portion through pivoting mechanism 112 (e.g., retainer 144 and ring 134) and angle bracket 116
25 into the housing interior to sensing assembly 110. Outer tube 158 is similar to and performs the
26 functions of the outer and guide tubes described above. The outer tube is rotatable about its
27 longitudinal axis via pivoting mechanism 112 (e.g., retainer 144 and ring 134), whereby the
28 interior of conical retainer 128 surrounds and forces the outer tube to rotate relative to the
29 housing when head 162 is pivoted via pivoting mechanism 112.

30 In order to sense endoscope tube manipulation, an inner tube 156 is disposed within outer
31 tube 158 to capture and emulate endoscope navigation tube motion as illustrated in Fig. 8.
32 Specifically, inner tube 156 includes cross-sectional dimensions less than the cross-sectional

1 dimensions of outer tube 158, whereby the inner tube is disposed in slidable relation within the
2 outer tube. A flexible torsion tube 148 is disposed at the proximal end of the inner tube, while
3 an instrument capture mechanism 138 is disposed at the proximal end of torsion tube 148. A
4 plurality of substantially annular spacers 150 are disposed about the torsion tube between the
5 inner tube and capture mechanism. The spacers are configured to maintain the torsion tube at
6 the approximate center of outer tube 158, while still permitting the torsion tube to flex within the
7 outer tube. Capture mechanism 138 is substantially similar to the instrument capture mechanism
8 described above. Inner tube 156 is initially positioned within outer tube 158 such that torsion
9 tube 148 flexes to traverse the outer tube curved portion and position the capture mechanism
10 adjacent nostril 136. When an endoscope navigation tube is inserted into the nostril, mechanism
11 138 captures the tube, thereby enabling inner tube 156 to emulate the endoscope navigation tube
12 manipulation and facilitate measurement of that manipulation via sensing assembly 110 in
13 substantially the same manner described above.

14 Pivoting mechanisms 112, 114 provide degrees of freedom that enable mock head 162
15 to be pivoted or rotated into various desired or appropriate positions for simulation. For
16 example, mock head 162 may be pivoted to a position as shown in Fig. 7, thereby simulating a
17 patient lying on their back. Further, head 162 may be pivoted from the patient back lying
18 position approximately ninety-degrees relative to housing 122, via mechanism 112, to simulate
19 a patient lying on their side. Moreover, head 162 may be pivoted from the patient side lying
20 position approximately ninety-degrees relative to the angle bracket, via mechanism 114, to
21 simulate a seated patient, while mechanism 112 may further enable pivoting of head 162 to
22 simulate a partially reclined seated patient. Thus, mock head 162 can be pivoted into multiple
23 positions via mechanisms 112, 114 that provide substantially orthogonal degrees of freedom.

24 Operation of interface device 120 is described with reference to Figs. 1, 7-8. Initially,
25 head 162 is manipulated via mechanisms 112, 114 to any desired position or orientation suitable
26 for a particular simulation. The medical procedure simulation system subsequently performs a
27 simulation in substantially the same manner described above. Specifically, a medical practitioner
28 or user manipulates an endoscope 22 and inserts navigation tube 49 into a bodily opening or
29 nostril of mock head 162. Navigation tube 49 interfaces capture mechanism 138, thereby
30 enabling inner tube 156 to reflect translational and rotational motion of the navigation tube.
31 Sensing assembly 110 measures the manipulation of the navigation tube and provides
32 information to computer system 25 via communications interface 24 to enable simulation of

1 force-feedback and traversal of the endoscope within a virtual patient.

2 Endovascular procedures generally require a medical practitioner to guide instruments
3 through a patient vascular system (e.g., including arteries and veins) to access a remote site of
4 interest where the instruments are utilized. The remote site may be located within or adjacent
5 a vein or artery, or may be located within the heart itself (e.g., during procedures of heart
6 valve repair or heart pacing leads placement or manipulation).

7 Generally, an endovascular procedure utilizes a variety of navigation and/or other
8 instruments or devices that are inserted into a patient body (e.g., through a vein) and
9 navigated, via the use of a fluoroscope display, to the site of the actual repair or intervention.
10 By way of example, a procedure may utilize a hollow sheath having a length of a few
11 centimeters and including a tapered, solid dilator that provides a conical tip for the sheath
12 assembly. The sheath provides an opening into a vein or artery, whereby the dilator is
13 removed from the sheath lumen and replaced by a catheter that is inserted into the sheath and
14 manipulated through the vein or artery based on a fluoroscope display to a site of interest. A
15 guidewire may be inserted into the catheter to extend beyond the catheter tip for navigation
16 around difficult passages in the patient vascular tree. The catheter may then be navigated by
17 the wire through the difficult passage.

18 During the procedure, the guidewire may be replaced by a more flexible or differently
19 shaped wire to maneuver around difficult anatomy, whereby a combination of the wires and
20 catheter may be utilized to reach a particular site. Additional instrument exchanges may be
21 employed for performing various functions. For example, a catheter having an angioplasty
22 balloon may be utilized as a surgical plaque removal device to alleviate circulation blockages
23 due to plaque. Alternatively, a stent may be deployed via a special catheter to maintain a
24 blood vessel in an open state or, where rupture is possible due to an aneurysm, a stent graft
25 may be deployed by the special catheter to both stabilize and reinforce the blood vessel at the
26 potential rupturing point.

27 During each procedure, the medical practitioner is required to control the depth (e.g.,
28 translational) and rotational orientation of the tips of several mutually co-axial instruments in
29 order to successfully complete that procedure. However, long flexible instruments (e.g.,
30 catheters, guidewires, etc.) exhibit torsional, compressive and tensile strain of varying
31 degrees, thereby preventing accurate determination of the orientation of the instrument distal
32 end based on observation of the instrument proximal end. In other words, the distance the

1 instrument is inserted within the body and the angle of rotation of the instrument distal end
2 are frequently a function of a large quantity of variables, such as the materials constructing
3 the instrument, the portion of the instrument disposed within the patient body, and the forces
4 encountered by the instrument.

5 In order to accommodate endovascular procedures, the interface device may
6 alternatively be configured to measure motion of a plurality of instruments at their respective
7 distal tips, and enable the instruments to be exchanged in any desired order during a
8 simulated procedure as illustrated in Fig. 9. The medical procedure simulation system
9 preferably simulates endovascular procedures and is similar to the system described above for
10 Fig. 1, except that the system of Fig. 9 includes interface device 314. Specifically, the
11 medical procedure simulation system includes computer system 25, interface device 314 and
12 communications interface 24 for transferring signals between computer system 25 and
13 interface device 314. The computer system and communications interface are substantially
14 similar to, and function in substantially the same manner as, the computer system and
15 communications interface described above. The simulation system simulates, via software, an
16 endovascular or other medical procedure, while displaying a simulated bodily region of
17 interest (e.g., the system includes models of the vascular system) on monitor 28. Interface
18 device 314 accommodates an actual or mock wire 302 optionally having a handle 308, an
19 actual or mock catheter 304 optionally having a handle 310, and an actual or mock sheath 306
20 optionally having a handle 312. The wire, catheter and sheath are nested and are partially
21 disposed within the interface device. The interface device measures manipulation of the wire,
22 catheter and sheath, and provides signals indicating the measured manipulation to computer
23 system 25 via communications interface 24. Computer system 25 processes the signals to
24 display, via monitor 28, the internal bodily region of interest, while adjusting the display (e.g.,
25 vascular models) to reflect manipulation of the wire, catheter and sheath. In addition,
26 interface device 314 may provide force feedback to the wire, catheter and sheath (e.g., oppose
27 or enable rotational and/or translational motion of these instruments) in accordance with
28 control signals from the computer system to simulate the forces encountered during an actual
29 procedure. Communications interface 24 transfers the manipulation and force feedback
30 signals between computer system 25 and interface device 314 in substantially the same
31 manner described above. It is to be understood that the interface device may interface various
32 instruments (e.g., endoscopes, tubes, navigation instruments, etc.) to a simulation system to

1 simulate a variety of medical procedures in substantially the same manner described below.

2 An exemplary instrument assembly for use in an interventional radiology procedure
3 and for interfacing computer system 25 via interface device 314 is illustrated in Fig. 10.

4 Specifically, an assembly 330 includes wire 302, catheter 304 and sheath 306. Catheter 304
5 is disposed within and extends beyond the sheath proximal and distal ends, while wire 302 is
6 disposed within and extends beyond the catheter proximal and distal ends. This nested
7 arrangement enables independent manipulation of the instruments in order to navigate within
8 a patient and utilize tools or other implements disposed at the distal ends of the instruments,
9 such as a balloon or other implement. The proximal portions of the wire, catheter and sheath
10 are each located external of the interface device, and each of these instruments may include a
11 corresponding handle 308, 310, 312 disposed toward their proximal end to enable
12 manipulation of that instrument. The distal portions of the instruments are similarly nested to
13 enable the interface device to measure manipulation of and apply force feedback to a
14 particular instrument.

15 An exemplary interface device for measuring manipulation of and providing force
16 feedback to a catheter is illustrated in Fig. 11a. Specifically, interface device 314 includes a
17 frame 410 having a base 430 and supports 432, 434, and a carrier assembly 412 disposed
18 between the supports. Support 432 extends from the proximal end of, and substantially
19 perpendicular to, the base, while support 434 extends from the distal end of the base
20 substantially parallel to support 432. An outer tube 416 is attached to frame 410 and extends
21 from support 432 toward carrier assembly 412, while an inner tube 414 is disposed within the
22 outer tube and extends beyond the outer tube distal end to the carrier assembly. The outer
23 tube includes cross-sectional dimensions greater than the cross-sectional dimensions of the
24 inner tube such that the inner and outer tubes are in slidable relation. The proximal end of
25 outer tube 416 is disposed within an opening or orifice 419 defined in support 432 for
26 receiving a distal end of a catheter 418. Since the catheter is flexible, the catheter tends to
27 buckle under compressive stress induced by translational motion of the catheter into the
28 interface device. However, the combination of the slidable inner tube and outer tube provide
29 a telescoping action that stabilizes the catheter and prevents buckling.

30 Support 432 further includes a pulley 420 disposed toward the support upper portion
31 and a corresponding conventional encoder 422. The encoder may be directly attached to the
32 pulley, but is preferably attached to the pulley via a shaft (not shown). Similarly, support 434

1 includes a pulley 426 disposed toward the support upper portion and a corresponding actuator
2 428. The actuator may be directly attached to pulley 426 or be attached via a shaft (not
3 shown). A belt 424 is disposed about each pulley 420, 426 and extends between the supports,
4 whereby the upper portion of the carrier assembly is connected to the belt.

5 Referring to Fig. 11b, carrier assembly 412 includes a platform 442 and a carrier
6 support 436 extending from the approximate center of and substantially perpendicular to the
7 platform. The platform bottom may include wheels or other devices (e.g., guide rails, tracks,
8 etc.) enabling movement of the carrier along the platform. An opening 438 is defined in the
9 carrier support, whereby inner tube 414 is attached to the carrier support coincident the
10 opening to enable catheter 418 to extend through that support. A carrier encoder 404,
11 preferably conventional, is disposed proximate the carrier support opening and includes a
12 tubular shaft 440 to receive the catheter. The catheter extends through the encoder tubular
13 shaft, whereby the shaft includes a set screw 403 to firmly grasp the distal end of the catheter.

14 Operation of interface device 314 is described with reference to Fig. 11a.
15 Specifically, catheter 418 is inserted into orifice 419 and manipulated by a user to traverse the
16 outer and inner tubes to carrier assembly 412. The catheter further extends through the carrier
17 support opening and encoder shaft, whereby the catheter is firmly engaged by set screw 403.
18 Once the catheter is engaged, further insertion of the catheter into the interface device by the
19 user causes the carrier assembly to move toward support 434. Conversely, force applied to
20 remove the catheter from the interface device causes the carrier assembly to move toward
21 support 432. The carrier assembly motion enables belt 424 to traverse and rotate pulleys 420,
22 426. Encoder 422 measures the rotational motion of pulley 420, and hence, the translational
23 motion of the catheter, and provides a signal to the computer system via the communications
24 interface. Rotational motion of the catheter enables tubular shaft 440 to rotate since the
25 catheter is connected to the shaft via set screw 403. Encoder 404 measures the rotational
26 motion of tube 440, and hence, the rotational motion of the catheter, and provides a signal to
27 the computer system via the communications interface. Thus, the interface device measures
28 both the translational and rotational motion of the catheter, whereby these motions are
29 partially dependent upon the force applied by the user to the catheter proximal end to enable
30 catheter motion.

31 The computer system processes the encoder signals to enable the simulation to reflect
32 catheter motion, and may provide control signals to actuator 428 to provide force feedback.

1 In particular, actuator 428 may apply force to pulley 426 to enhance or oppose the catheter
2 translational motion. The applied force may impede pulley and belt motion, thereby requiring
3 additional force to manipulate the catheter. Conversely, the applied force may facilitate
4 rotation of the pulley and enhance belt motion, thereby requiring less force to manipulate the
5 catheter. The actuator applies force to pulley 426 in accordance with control signals
6 determined by the computer system, whereby the forces may cause catheter 418 to store a
7 certain amount of hysteresis or play for both translational and rotational motion (e.g.,
8 compression or stretching). This hysteresis or play is the difference between observed
9 rotational and/or translational motion at the proximal and distal ends of catheter 418.

10 An alternative embodiment of interface device 314 is illustrated in Fig. 12.
11 Specifically, interface device 314 includes a frame 504 having a base 540 and supports 542,
12 544, and a carriage assembly 520 disposed between the supports. Base 540 includes legs 528,
13 preferably constructed of rubber, to stabilize the device. Support 542 extends from a
14 proximal portion of, and substantially perpendicular to, base 540, while support 544 extends
15 from the distal end of the base substantially parallel to support 542. A bracket 506 is disposed
16 proximally of support 542 on base 540, and supports a pulley 510 and an actuator 508
17 connected to the pulley via a shaft. A pulley 514 is disposed at a base distal end, whereby a
18 belt 512 extends between and about the pulleys. Support 542 includes an opening 505 that
19 receives a tube 502. The tube extends from the support to an orifice 501 defined in a plate
20 503 that is placed over the device proximal portion and includes a mock bodily region (not
21 shown). Tube 502 is typically mounted within a foam block 509 to provide resiliency and
22 emulate forces and movement of the entry site of a body encountered during a medical
23 procedure. Tube 502 receives a catheter 500 and guides the catheter into the device.

24 Guide rods 516, 518 extend between supports 542, 544 and enable carriage assembly
25 520 to traverse base 540. Guide rod 516 extends between the upper portions of the supports,
26 while guide rod 518 is disposed below and substantially parallel with guide rod 516, toward
27 base 540. Further, an encoder bar or strip 526 extends between the supports adjacent guide
28 rod 516 to enable measurement of catheter motion as described below. A bellows or
29 stabilizer 522 is disposed between support 542 and the carriage assembly to prevent catheter
30 500 from buckling. Bellows 522 includes multiple leaves or sections 546 with each section
31 adjoined via a hinge or fold and having guide openings 523, 525 and a stabilization opening
32 521. Guide openings 523, 525 are defined in each bellows section to receive and fit loosely

1 over corresponding guide rods 516, 518, respectively, while stabilization opening 521 is
2 defined toward the approximate center of each section to receive and prevent buckling of the
3 catheter. The bellows is supported by guide rods 516, 518, and is typically not directly
4 connected to the supports or carriage assembly.

5 The bellows is typically formed of a sheet of a thin, rigid substance, such as plastic,
6 that is die or laser cut and subsequently folded. The hinges or folds of bellows 522 are
7 preferably formed by removing a sufficient quantity of material, thereby providing a spring
8 type action inducing the bellows to expand proportionally as carriage assembly 520 moves
9 toward support 544. This enables stabilization holes 521 to be maintained at a relatively
10 uniform distance, whereby this distance is sufficient to support the catheter and prevent
11 buckling when the catheter is advanced into the interface device under typical amounts of
12 translational force. Thus, the bellows serves to stabilize the catheter, similar to the function
13 of the telescoping tubes described above. However, the bellows may expand to a length
14 substantially greater than its length in a compressed state, thereby providing enhanced
15 accommodation of multiple lumens (e.g., sheath, catheter and wire).

16 Referring to Figs. 13a-13b, carriage assembly 520 includes a carriage 562, preferably
17 a machined block of aluminum, having a guide 590 disposed on a top surface to engage guide
18 rod 516, and a channel 592 formed through the carriage to engage guide rod 518. A fastener
19 596 extends down from a carriage side to engage belt 512 (Fig. 12), while an encoder 524 is
20 disposed adjacent guide 590. A catheter channel 594 is formed through the intermediate
21 portion of the carriage to receive catheter 500 from bellows 522. A collet bearing 566 is
22 typically pressed into the distal portion of carriage 562 coincident channel 594. A collet 568
23 is disposed within bearing 566 such that the collet is rotatably coupled to carriage 562. A
24 compression ring 574 is further disposed about the collet within a compression groove 569.
25 The collet further includes relief holes 571, defined in the intermediate portion of the collet,
26 and saw kerfs 573 that serve to separate the distal end of the collet into gripper jaws 567. The
27 collet is tubular, preferably including a central channel, to enable instruments, such as
28 catheters, wires and sheaths, to be inserted through the collet. Instruments having an
29 appropriate dimension may be grasped by gripper jaws 567, while instruments having lesser
30 dimensions may extend through the collet.

31 A spring 576 is disposed over collet 568, whereby the spring and collet are positioned
32 within carriage 562. A collet expander 578 is inserted into carriage 562 adjacent spring 576

1 to compress that spring. A retainer 580 is disposed proximate the expander to maintain the
2 collet expander and associated components within the carriage. A lever 582 is attached to
3 carriage 562, via a pin 564, to control collet 568. In particular, when lever 582 is pivoted
4 counterclockwise (e.g., toward support 542), the lever causes collet expander 578 to compress
5 spring 576, thereby expanding jaws 567 to an open state. Conversely, pivoting the lever in a
6 clockwise direction (e.g., toward support 544) enables expansion of spring 576 and
7 compression of the jaws to a closed state.

8 An encoder disk 550 is pressed onto the proximal end of collet 568, while an
9 encoder sensor 558 fits over the disk and is attached to carriage 562. Each of the above-
10 described elements of the carriage assembly includes an opening to enable instruments, such
11 as catheters, to be inserted into and/or through the assembly depending upon instrument
12 dimensions as described above. Stabilization holes 521 are maintained coincident the
13 element openings to stabilize the instrument and enable the instrument to be inserted into the
14 carriage assembly. The carriage assembly traverses frame 504 via guide rods 516, 518 and is
15 limited to translational motion as described below.

16 Operation of the collet to engage an appropriately dimensioned instrument is
17 illustrated in Figs. 14a-14d. Specifically, lever 582 is pivoted about pivot pin 564 in a
18 counterclockwise direction (e.g., toward the interface device proximal end), thereby forcing
19 collet expander 578, disposed proximate the lever, further into the carriage assembly. The
20 collet expander compresses spring 576, and includes a conical proximal tip that separates the
21 collet distal end to enable jaws 567 to enter an open state for receiving an appropriately
22 dimensioned instrument (Fig. 14a).

23 Once the collet jaws have entered an open state, an instrument, such as catheter 500, is
24 inserted into the interface device and through the collet (Fig. 14b). Lever 582 is subsequently
25 released (e.g., pivoted toward the interface device distal end), thereby allowing spring 576 to
26 enter an expanded state. The spring forces collet expander 578 against retainer 580, and
27 permits jaws 567 to enter their normally closed state to grasp catheter 500 (Fig. 14c).

28 The collet proximal portion is attached to encoder disk 550, whereby the collet rotates,
29 via bearing 566, to reflect catheter rotation. Encoder disk 550 similarly rotates with collet
30 568, whereby encoder sensor 558 senses marks on the disk to measure rotation of the disk and
31 the catheter.

32 The collets may be of varying dimensions to enable capture of a particular instrument.

1 By way of example only, an assembly including wire 632, inner catheter 630 and catheter
2 500 is inserted into carriage 562 (Fig. 14d), whereby each of these instruments is
3 independently manipulable. The collet includes sufficient dimensions to enable the assembly
4 to traverse the carriage, while permitting jaws 567 to grasp catheter 500 in substantially the
5 same manner described above. The carriage assembly thus measures motion of catheter 500,
6 while wire 632 and inner catheter 630 extend to corresponding carriages (e.g., Fig 15) having
7 appropriately dimensioned collets to grasp and measure motion of these instruments in
8 substantially the same manner described above.

9 Operation of the interface device is described with reference to Figs. 12 and 13a-13b.
10 Specifically, catheter 500 is inserted into orifice 501 by a user and traverses tube 502 and
11 bellows 522 until being engaged by collet 568 of carriage assembly 520. Lever extension 583
12 is manipulated toward support 544 to pivot lever 582 and enable the collet to grasp the
13 catheter as described above. The lever may alternatively be forced toward the interface
14 device proximal end to actuate a quick-release as described above. Further insertion of
15 catheter 500 into the interface device by the user forces carriage 520 to move toward support
16 544. As the carriage assembly traverses the base, encoder 524 senses marks on encoder bar
17 526 to measure translational motion of the carriage assembly, and hence, the catheter. The
18 translational motion measured by the encoder differs from the translational motion of the
19 catheter relative to the orifice since the catheter is subject to expansion and compression due
20 to forces exerted by the user. The encoder provides a signal indicating the measured
21 translational motion of the catheter to the computer system via the communications interface.
22 Similarly, rotational motion of the catheter rotates encoder disk 550, thereby enabling sensor
23 558 to measure that rotational motion. The sensor provides a signal indicating the measured
24 rotational motion to the computer system via the communications interface. The computer
25 system processes the signals to update the display and determine force feedback signals.

26 Force feedback is accomplished via actuator 508 affecting pulley motion. Since the
27 carriage assembly is connected to belt 512, the carriage assembly motion causes belt 512 to
28 traverse and rotate pulleys 510, 514. Control signals from the computer system control the
29 actuator to impede or enhance rotation of pulley 510. When pulley rotation is impeded,
30 additional force is required to manipulate translational motion of the catheter, while
31 enhancing pulley rotation enables less force to manipulate the catheter. Force feedback is
32 typically utilized to simulate forces encountered during an actual procedure when inserting or

1 removing a catheter within a patient. Thus, the user feels at the proximal end of the
2 instrument forces imparted to the instrument distal end based on a simulated procedure.

3 An alternative interface device configuration for accommodating nested and/or
4 independently inserted instruments is illustrated in Fig. 15. The interface device is
5 substantially similar to, and functions in substantially the same manner as, the interface
6 device described above for Figs. 12, 13a-13b and 14a-14d except that the interface device of
7 Fig. 15 accommodates nested and/or independently inserted instruments. Specifically, the
8 interface device includes a base 700 for receiving frame 504 and its associated components,
9 and a cover 704. The cover proximal portion typically includes openings or mock orifices
10 712 of a simulated anatomy (not shown), typically mounted on a platform 702, to enable
11 instruments to be inserted into the interface device. Platform 702 generally includes openings
12 714 defined in the plate coincident orifices 712 to enable insertion of instruments into the
13 interface device. Tubes 502 extend from orifices 712 to guide the instruments into the
14 interface device. Tubes 502 may be disposed in a foam block (not shown) as described
15 above.

16 Frame 504 is substantially similar to the frame described above for Fig. 12 and
17 includes components for accommodating independently inserted instruments. The
18 independently inserted instruments are accommodated by respective configurations 722 and
19 724 arranged in parallel relation. Configuration 724 is substantially similar to, and functions
20 in substantially the same manner as, the configuration of Fig. 12 and receives an instrument,
21 such as a catheter, through tube 502. Catheter motion is measured by carriage assembly 520,
22 whereby signals indicating the measured motion are provided to the computer system to
23 determine force feedback and update the display in substantially the same manner described
24 above.

25 Configuration 722 is substantially similar to configuration 724 except that
26 configuration 722 includes a plurality of carriage assemblies and corresponding bellows,
27 belts, pulleys and actuators to measure manipulation of nested instruments, such as the wire,
28 catheter and sheath assembly. In particular, configuration 722 includes brackets 716, 718,
29 720 disposed toward the frame proximal end having corresponding pulleys 726, 728, 730 and
30 actuators 736, 738, 740. A plurality of corresponding pulleys (partially shown) are disposed
31 at the frame distal end. Carriage assemblies 706, 708, 710 are substantially similar to and
32 measure rotational and translational motion of a corresponding instrument in substantially the

1 same manner described above for carriage assembly 520. Carriage assemblies 706, 708, 710
2 are each connected to respective belts disposed about and extending between the proximal
3 and distal (partially shown) pulleys. The actuators and pulleys enable the carriage assemblies
4 to provide force feedback to the particular instrument engaged by that assembly in
5 substantially the same manner described above for carriage assembly 520. Bellows 522 are
6 disposed between support 542 and carriage assembly 706, between carriage assemblies 706
7 and 708 and between carriage assemblies 708 and 710, to prevent buckling of the particular
8 instruments as described above. The interface device may include any quantity (e.g., at least
9 one) of configurations each having any quantity (e.g., at least one) of carriage assemblies to
10 accommodate any desired quantity of instruments.

11 The arrangement of carriage assemblies to accommodate nested instruments is
12 illustrated in Fig. 16. Specifically, instrument assembly 330 (e.g., including wire 302,
13 catheter 304 and sheath 306) is inserted into configuration 722 of the interface device and
14 through a bellows 522 (not shown), whereby carriage assembly 706 includes a collet 568 of
15 sufficient dimension to grasp the sheath as described above. The catheter and wire pass
16 through carriage assembly 706 and extend through a bellows 522 (not shown) to carriage
17 assembly 708 having a collet 568 of sufficient dimension to grasp the catheter. The wire
18 further passes through carriage assembly 708 and extends through a bellows 522 (not shown)
19 to carriage assembly 710 having a collet 568 of sufficient dimension to grasp the wire. The
20 carriage assemblies each traverse guide rods 516 and 518 (not shown) and measure
21 manipulation of and provide force feedback to the respective instruments as described above.

22 Operation of the interface device is described with reference to Fig. 15. Specifically,
23 an instrument assembly (not shown e.g., including a wire, catheter and sheath) and another
24 instrument (e.g., a catheter) are inserted by a user through corresponding orifices 712, 714
25 and traverse tube 502 to extend to the carriage assemblies. Configuration 724 measures
26 manipulation of the instrument (e.g., catheter) as described above, while the instrument
27 assembly extends through carriage assemblies 706, 708 and 710. Each carriage assembly
28 706, 708, 710 includes a collet of an appropriate dimension and captures, measures
29 manipulation of, and provides force feedback to, a particular instrument (e.g., sheath, catheter
30 and wire, respectively) as described above. Configurations 722, 724 operate in parallel to
31 provide the computer system with measured manipulation signals for their corresponding
32 instruments to enable the computer system to determine force feedback and update the display

1 to reflect the manipulations for each instrument in substantially the same manner described
2 above. Similarly, the interface device of Fig. 11a may include plural carrier assemblies to
3 handle plural instruments, similar to the manner described above.

4 In order to enable automatic capture and release of instruments, the interface device
5 may further include an automatic capture and release mechanism as illustrated in Figs. 17a-
6 17b. The interface device includes a configuration, similar to configuration 724 described
7 above for Fig. 15, having carriage assemblies 706 (not shown), 708, 710 separated by bellows
8 (not shown) and arranged in a manner substantially similar to Fig. 16. The mechanism is
9 described with reference to carriage assemblies 708, 710 for illustrative purposes, whereby
10 the mechanism may equally be employed between the remaining carriage assemblies or a
11 carriage assembly and the frame as described below. Carriage assemblies 708, 710 are
12 substantially similar to carriage assemblies 708, 710 described above except that the carriage
13 assemblies further include components to facilitate an automatic capture and release
14 mechanism. Specifically, carriage assembly 710 includes a bracket 814 extending from the
15 carriage assembly upper portion, while carriage assembly 708 includes a bracket 806
16 extending from its upper portion. A rod 804 is disposed through openings defined in brackets
17 806, 814 to couple carriage assemblies 708, 710.

18 Bracket 814 includes a spring screw 816 having a spring-loaded nylon plunger to
19 engage rod 804. The spring screw may be adjusted to control application of frictional force to
20 rod 804, thereby simulating friction that may be encountered between nested instruments
21 (e.g., wire 302 and catheter 304). Bracket 806 includes a set screw 808 for engaging rod 804,
22 whereby translational motion of the rod is initiated in response to translational motion of
23 carriage assembly 708. A stop 818 is disposed toward the distal end of rod 804 via a set
24 screw 820. The stop limits the distance that wire 302 may be inserted into the interface
25 device relative to catheter 304. This may be utilized to simulate hollow devices having a
26 closed end, such as a heart placing lead. Generally, a wire stylet is utilized to stiffen the lead
27 for navigation into the heart, whereby the stylet is removed at the completion of the procedure
28 to return the lead to a flexible state. Additional stylet insertion is typically prevented by the
29 end of the lead, which may be simulated by adjustment of stop 818.

30 A traveler 810 is secured to rod 804 via a set screw 812. The traveler is typically
31 implemented by a 'T' shaped bracket, preferably rotated approximately ninety degrees, and
32 moves translationally with rod 804 in response to translational motion of carriage assembly

1 708. In other words, differential translation of carriage assembly 708 with respect to carriage
2 assembly 710 causes differential motion of traveler 810 relative to carriage assembly 710.
3 The amount of rod motion is partially determined by the frictional force applied to the rod by
4 spring screw 816. The traveler is preferably disposed on rod 804 coincident a portion of
5 carriage assembly 710. In addition, lever extension 583 includes a projection 840 that
6 extends beyond pivot pin 564 and interfaces rod 804 via an opening defined in the projection.
7 The projection interfaces a portion of rod 804 disposed between bracket 814 and traveler
8 810. Traveler 810 manipulates projection 840 to pivot lever extension 583 in order to capture
9 and release instruments as described below.

10 Carriage assembly 710 further includes a rocker 824, tension spring 832, rocker pivot
11 pin 826, a fixed pin 828, movable pin 830 and stop pin 838, each disposed toward the upper
12 portion of the carriage assembly. Rocker 824 is preferably implemented by an 'L' shaped
13 bracket having linear sections 842, 844. Rocker 824 pivots about rocker pivot pin 826
14 disposed toward the interface or joining point of the rocker linear sections. Movable pin 830
15 is disposed toward the distal end of linear section 844 and moves in conjunction with rocker
16 motion. Fixed pin 828 is disposed distally of rocker 824, whereby tension spring 832 is
17 disposed between and coupled to the fixed and movable pins. The tension spring is utilized
18 to force traveler 810 against projection 840 to overcome the bias of a lever spring (e.g.,
19 spring 576 of Fig. 13a) to manipulate the lever and capture and release instruments as
20 described below. Stop pin 838 is disposed proximally of pivot pin 826 to limit rotation of
21 rocker 824 as described below.

22 Exemplary operation of the automatic capture and release mechanism is described.
23 Initially, wire 302 is captured by carriage assembly 710, while catheter 304 is captured by
24 carriage assembly 708 (Fig. 17a). When wire 302 is withdrawn from the interface device,
25 carriage assembly 710 is drawn toward carriage assembly 708, while carriage assembly 708
26 remains relatively stationery (e.g., since wire 302 passed through carriage assembly 708,
27 while carriage assembly 708 engages catheter 304). Rocker 824 is initially positioned against
28 stop pin 838 by clockwise torque applied by spring 832, with section 842 oriented to interface
29 traveler 810. As rocker 824 is drawn toward traveler 810, section 842 interfaces the traveler,
30 thereby causing the rocker to rotate about pivot pin 826 in a counterclockwise direction.
31 Tension spring 832 exerts a force on movable pin 830 to exert a torque on the rocker. When
32 rocker 824 rotates a sufficient amount to enable linear section 844 to be proximate the

1 proximal side of traveler 810, the direction of torque applied by tension spring 832 to rocker
2 824 changes to a counterclockwise direction. As the rocker further rotates, the torque
3 increases and section 844 interfaces the proximal side of traveler 810, thereby moving the
4 traveler distally relative to carriage assembly 710. The traveler contacts projection 840, and
5 pivots lever extension 583 toward carriage assembly 710 in response to overcoming the bias
6 forces on the lever to release wire 302 (Fig. 17b). Wire 302 is released from carriage
7 assembly 710, and carriage assemblies 708, 710 maintain their positions relative to each other
8 due to the tension of spring 832 holding extension 844 against the proximal side of traveler
9 810. The wire may be withdrawn and exchanged for another instrument as described below.

10 A new instrument may be inserted through catheter 304 and into the interface device.
11 The instrument is inserted to extend to carriage assembly 710. Additional insertion force
12 causes carriage assembly 710 to move distally and away from carriage assembly 708. Section
13 844 of rocker 824 interfaces traveler 810, whereby the rocker is subsequently pivoted in a
14 clockwise direction. As rocker 824 rotates, the torque applied by spring 832 decreases in the
15 counterclockwise direction and ultimately changes to a clockwise direction. Stop pin 838
16 limits rotation of rocker 824 when the rocker rotates sufficiently to enable section 842 to be
17 positioned proximate the distal side of traveler 810. The spring bias of lever extension 583
18 pivots the lever to capture the new instrument (Fig. 17a) as described above. Thus, the
19 mechanism enables insertion or changing of instruments during a simulated procedure in a
20 realistic manner without requiring manual pivoting of lever extension 583.

21 The automatic capture and release mechanism described above is generally employed
22 between carriage assemblies 708, 710, between carriage assemblies 706, 708 (Figs. 15 and
23 16), and between carriage assembly 706 and a frame proximal end or support in substantially
24 the same manner described above. Specifically, each carriage assembly 706, 708, 710
25 typically includes the mechanism components of carriage assemblies 708, 710 described
26 above (e.g., components 806 and 890 shown on carriage assembly 708 in Figs. 17a-17b). The
27 appropriate components (e.g., the carriage assemblies may not include or utilize some
28 components; for example, bracket 806 of carriage assembly 710 (not shown) is typically not
29 utilized since that assembly is not coupled to subsequent assemblies in the particular
30 arrangement) are arranged to interface a corresponding rod as described above, whereby an
31 independent rod is disposed between carriage assemblies 708, 710, between carriage
32 assemblies 706, 708, and between carriage assembly 706 and an interface device frame. The

1 rod associated with carriage assembly 706 is attached to the frame to serve as a ground,
2 similar to the function of bracket 806 described above. The mechanism is implemented to
3 facilitate automatic capture and release of the sheath, catheter and wire by respective carriage
4 assemblers 706, 708, 710 in substantially the same manner described above. In addition, the
5 automatic capture and release mechanism may alternatively utilize magnets (e.g., a magnet
6 disposed on a carriage assembly and another magnet disposed on rod 804 or other support) to
7 generate a magnetic force to overcome the lever bias and pivot the lever to desired positions,
8 similar to the magnets described above for Fig. 3. Similarly, the automatic capture and
9 release mechanism may be utilized in the system of Fig. 3 to maintain the inner tube within
10 the outer tube. The mechanism components may be attached to the inner and outer tubes in a
11 manner similar to the carriage assembly arrangement described above.

12 It will be appreciated that the embodiments described above and illustrated in the
13 drawings represent only a few of the many ways of implementing an interface device and
14 method for interfacing instruments to medical procedure simulation systems.

15 The interface devices of the present invention may be utilized with various elongated
16 or other instruments (e.g., endoscopes, catheters, wires, sheaths, etc.) for simulating a variety
17 of medical procedures, and are not limited to the specific instruments or applications
18 disclosed herein. The computer system of the medical procedure simulation system may be
19 implemented by any conventional or other processing system. The communications interface
20 may include any circuitry (e.g., analog to digital converters, digital to analog converters, etc.)
21 and/or processors to transfer and/or convert signals for compatibility between an interface
22 device and processing system. The functions of the communications interface may further be
23 performed within the interface device or processing system.

24 The endoscope or other instruments may include various switches, buttons, dials or
25 levers to simulate various events. For example, the endoscope switches may be used to
26 simulate irrigation and suction and video captures including freeze frame and returning to
27 dynamic video capture. The interface device and instrument capture mechanism may be
28 utilized with actual endoscopes to permit medical practitioners to train with instruments used
29 during endoscopic procedures. The endoscope may further include force feedback on the
30 various switches or levers. The force feedback may be applied by an actuator configured to
31 apply a static or dynamic force to the endoscope component. The actuator may be adjusted to
32 provide a desired force.

1 The encoders of the interface devices and instruments may be implemented by any
2 conventional or other encoders or devices, such as an optical encoder, an analog encoder or a
3 potentiometer. The translational encoders of the interface devices may alternatively be
4 implemented by a linear encoder reading a linear target strip, typically including light and
5 dark bands, disposed along a motion path of the trolley, carrier or carriage. Force feedback
6 may be provided by the interface devices via a passive or active braking mechanism or an
7 active motor or other actuator attached to the trolley, carrier or carriage that utilizes frictional
8 forces to impede motion (e.g., friction force against the frame, guide rods or guide rails).
9 Moreover, additional force feedback units may be employed, similar to force feedback units
10 described above, to impede rotational motion of instruments.

11 The interface devices may utilize any anatomical sites, such as a nostril, mouth, ear,
12 anus, urethra, etc. Further, any types of orifices may be utilized such as orifices made
13 surgically (e.g., an opening made in the stomach for laproscopic procedures). The interface
14 devices described above may each include a pivotable entry site, whereby the site may be
15 pivoted to any desired position or orientation. Moreover, the interface devices may include
16 any conventional or other types of pivoting mechanisms that can pivot the site in any quantity
17 of or any particular degree of freedom. The simulation system may similarly simulate any
18 desired anatomical site or orifice. In addition, the interface devices may include additional
19 encoders as described above to measure the entry site orientation and enable the simulation
20 system to simulate a procedure based on that orientation.

21 The capture mechanism may be implemented by any conventional or other devices,
22 such as a collet (e.g., any type of standard collet (e.g., spring or screws)), chuck, quick
23 connect (e.g., standard quick connects, such as those used for high pressure hoses), or quick-
24 disconnect type devices that enable transmission of force and torque. The capture mechanism
25 may utilize mechanical, magnetic (e.g., solenoid and plunger), air pressure, or other devices to
26 effect capture. The automatic capture mechanism may utilize sensors and computer control to
27 sense when to capture and release. Further, the present invention generally utilizes female
28 type capture mechanisms, however, an instrument may be modified at the tip to fit over an
29 expandable male fitting inside the interface device (e.g., scissors type, balloon, balls forced
30 outward by a conical wedge, etc.). The capture mechanism and collet may be of any size or
31 shape to accommodate a particular instrument. The carrier or carriage may be supported via
32 guide rods, but may alternatively be supported via air bearings where the carrier or carriage

1 includes a flat base supported by a surface with holes through which air is forced providing a
2 thin layer of air between the carrier or carriage and support surface, thus a very low friction
3 carrier or carriage friction guide. The carriage may utilize any conventional levers or
4 switches manipulated in any fashion to facilitate capture and release. An interface device
5 may include any quantity (e.g., at least one) of trolleys, carriers and carriages to accommodate
6 any quantity of nested or other instruments.

7 The various encoders, actuators, pulleys, belts and other components of the present
8 invention may be implemented by any conventional or other types of components performing
9 the above-described functions. The components may be of any shape or size, may be
10 constructed of any suitable materials, and may be arranged in any fashion within the interface
11 devices. The trolley, carrier and carriages may be of any shape or size, and may move via any
12 conventional or other devices, such as wheels, guide rails, tracks, sufficient slippery surface
13 including air bearings, etc. The belts may be constructed of any suitable material, and may be
14 implemented by any belt, cable, rope, chain or other suitable device. The belts may be
15 disposed in any fashion within the interface device. The pulleys may be implemented by any
16 type of pulley, gear or other device compatible with the belt. The interface device housing,
17 frame and components may be of any size or shape, and may be constructed of any suitable
18 materials. The various tubes (e.g., inner, outer, guide, etc.) of the interface devices may be of
19 any size, shape or length, and may be constructed of any suitable materials.

20 The set screws utilized in the present invention may be implemented by any
21 conventional set screws or any other conventional device for grasping an instrument. The
22 inner or other interface device tubes may be attached to the frame and/or trolley, carrier, or
23 carriage via any conventional or other techniques. The bellows may be of any quantity, shape
24 or size and may be constructed of any suitable materials. The bellows may be implemented
25 by any device capable of supporting an instrument and preventing buckling. In particular, the
26 anti-buckling function provided by telescoping tubes or by bellows herein may also be
27 provided by a tube which has been slit to enable a portion of the carriage (e.g. the capture
28 mechanism and zero or more sensors) and the medical tool to move inside the tube while the
29 remainder of the carriage moves outside the slit. The slit is of sufficiently small width to
30 prevent the medical tool from buckling out through the slit, but is of a sufficiently wide
31 dimension so as to allow the two portions of the carriage inside and outside the tube to be
32 coupled. A long hole drilled close to and parallel to the surface of a solid material, with a slit

1 cut into the material extending into the hole may be substituted for the slit tube. The foam
2 block may be implemented by any sufficiently resilient material. The automatic capture
3 mechanism may utilize rods of any quantity (e.g., at least one), shape (e.g., round or
4 rectangular) or size. The mechanism may utilize any mechanical, electrical or other forces to
5 pivot the lever for capture or release, such as magnets, springs, rubber bands, etc. Similarly,
6 these devices may be utilized with the inner and outer tube mechanism to enable capture and
7 release. The mechanism may be employed in any quantity to automatically engage particular
8 instruments, and may extend to any number of mutually coaxial instruments.

9 The various interface device embodiments may be implemented either individually or
10 in any combination to accommodate various instruments. Further, the various manners of
11 measuring instrument manipulation and providing force feedback within the interface devices
12 may be utilized in any of the above-described embodiments.

13 It is to be understood that the terms “upper”, “lower”, “top”, “bottom”, “side”,
14 “length”, “up”, “down”, “front”, “rear”, “back”, “clockwise” and “counterclockwise” are
15 used herein merely to describe points of reference and do not limit the present invention to
16 any specific configuration or orientation.

17 From the foregoing description, it will be appreciated that the invention makes
18 available a novel interface device and method for interfacing instruments to medical
19 procedure simulation systems wherein various instruments are interfaced to a medical
20 procedure simulation system to simulate performance of a variety of medical procedures.

21 Having described preferred embodiments of a new and improved interface device and
22 method for interfacing instruments to medical procedure simulation systems, it is believed
23 that other modifications, variations and changes will be suggested to those skilled in the art in
24 view of the teachings set forth herein. It is therefore to be understood that all such variations,
25 modifications and changes are believed to fall within the scope of the present invention as
26 defined by the appended claims.

What is claimed is:

- 1 1. An interface device for interfacing instruments to a simulation system to
2 enable a user to interact with the simulation system to perform a medical procedure on a
3 simulated anatomy of a virtual patient, said interface device comprising:
4 a peripheral in the form of a mock medical instrument capable of selective
5 manipulation by the user;
6 an orifice for receiving said instrument;
7 a guide tube for directing said instrument from said orifice into said interface device;
8 a capture mechanism for engaging said instrument to enable said interface device to
9 measure manipulation of and provide force feedback to said instrument; and
10 a sensing assembly to measure manipulation of and provide force feedback to said
11 instrument, wherein said sensing assembly includes:
12 motion detection means to measure manipulation of said captured instrument
13 and provide signals indicating said measured manipulation to said simulation system
14 to simulate said medical procedure; and
15 force application means to apply force feedback to said captured instrument in
16 response to control signals from said simulation system.
- 1 2. The device of claim 1 wherein said instrument includes an endoscope.
- 1 3. The device of claim 1 wherein said instrument includes a nested instrument
2 assembly, and said interface device further includes:
3 a plurality of capture mechanisms each engaging a corresponding instrument
4 of said instrument assembly to enable said interface device to measure manipulation
5 of and provide force feedback to that instrument; and
6 a plurality of sensing assemblies each measuring manipulation of and
7 providing force feedback to said corresponding instrument.
- 1 4. The device of claim 1 wherein said interface device further includes a pivoting
2 mechanism to pivot said orifice.

1 5. An interface device for interfacing instruments to a simulation system to
2 enable a user to interact with the simulation system to perform a medical procedure on a
3 simulated anatomy of a virtual patient, said interface device comprising:
4 a plurality of peripherals in the form of mock medical instruments capable of selective
5 manipulation by the user;
6 a plurality of orifices for receiving said instruments;
7 a plurality of guide tubes for directing said instruments from said orifices into said
8 interface device;
9 a plurality of capture mechanisms for engaging said instruments to enable said
10 interface device to measure manipulation of and provide force feedback to said instruments;
11 and
12 a plurality of sensing assemblies to measure manipulation of and provide force
13 feedback to said instruments, wherein each said sensing assembly includes:
14 motion detection means to measure manipulation of a corresponding captured
15 instrument and provide signals indicating said measured manipulation to said
16 simulation system to simulate said medical procedure; and
17 force application means to apply force feedback to said corresponding
18 captured instrument in response to control signals from said simulation system.

1 6. The device of claim 5 wherein at least one of said instruments includes a nested
2 instrument assembly.

1 7. In an interface device for interfacing instruments to a simulation system to
2 enable a user to interact with the simulation system to perform a medical procedure, a capture
3 mechanism for engaging an instrument inserted within the interface device to enable the
4 interface device to measure manipulation of and provide force feedback to that instrument,
5 said capture mechanism comprising:
6 a grasping member for engaging said instrument to enable said interface device to
7 measure manipulation of and provide force feedback to said instrument; and
8 an actuator for activating said grasping member to engage said instrument in response
9 to user manipulation of said instrument.

1 8. A method for interfacing instruments to a simulation system, via an interface
2 device, to enable a user to interact with the simulation system to perform a medical procedure
3 on a simulated anatomy of a virtual patient, said method comprising the steps of:

4 (a) inserting a peripheral in the form of a mock medical instrument into said interface
5 device via an orifice and guide tube, and selectively manipulating said instrument within said
6 interface device;

7 (b) engaging said instrument, via a capture mechanism, to enable said interface
8 device to measure manipulation of and provide force feedback to said instrument;

9 (c) measuring manipulation of said captured instrument and providing signals
10 indicating said measured manipulation to said simulation system to simulate said medical
11 procedure; and

12 (d) applying force feedback to said captured instrument in response to control signals
13 from said simulation system.

1 9. The method of claim 8 wherein said instrument includes an endoscope.

1 10. The method of claim 8 wherein said instrument includes a nested instrument
2 assembly, and step (b) further includes:

3 (b.1) engaging each instrument of said instrument assembly to enable said
4 interface device to measure manipulation of and provide force feedback to that
5 instrument;

6 step (c) further includes:

7 (c.1) measuring manipulation of said each instrument and providing signals
8 indicating said measured manipulation to said simulation system; and

9 step (d) further includes:

10 (d.1) applying force feedback to said each instrument in response to control
11 signals from said simulation system.

1 11. The method of claim 8 wherein step (a) further includes:

2 (a.1) pivoting said orifice to a desired orientation.

ABSTRACT

1 An interface device and method for interfacing instruments to a medical procedure
2 simulation system serve to interface peripherals in the form of mock medical instruments to
3 the medical procedure simulation system computer to enable simulation of medical
4 procedures. The interface device includes a housing having a mock bodily region of interest
5 to facilitate insertion of a mock instrument, such as an endoscope tube, into the interface
6 device. The mock bodily region of interest may be pivotable to simulate various patient
7 orientations. The instrument is engaged by a capture mechanism in order to measure
8 rotational and translational motion of the instrument. An actuator is disposed within the
9 interface device to provide force feedback to the instrument. The measured motion is
10 provided to the computer system to reflect instrument motion on the display during the
11 simulation. Alternatively, the interface device may be configured to accommodate instrument
12 assemblies having a plurality of nested instruments (e.g., sheath, catheter and wire), whereby
13 the interface device individually grasps, measures manipulation of and provides force
14 feedback to the nested instruments. In addition, the interface device may be configured to
15 simultaneously accommodate a plurality of independently inserted instruments.

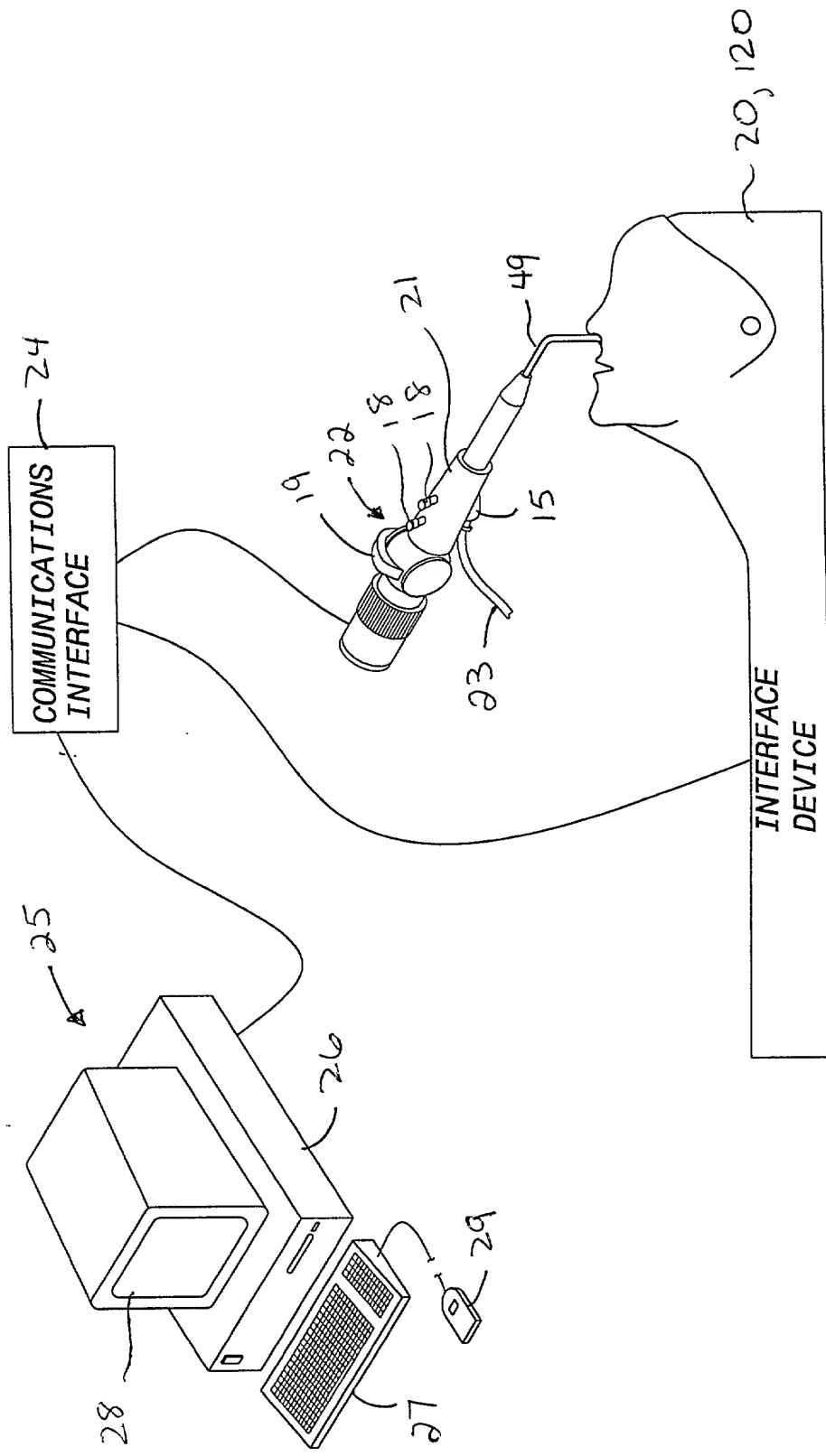


Fig. 1

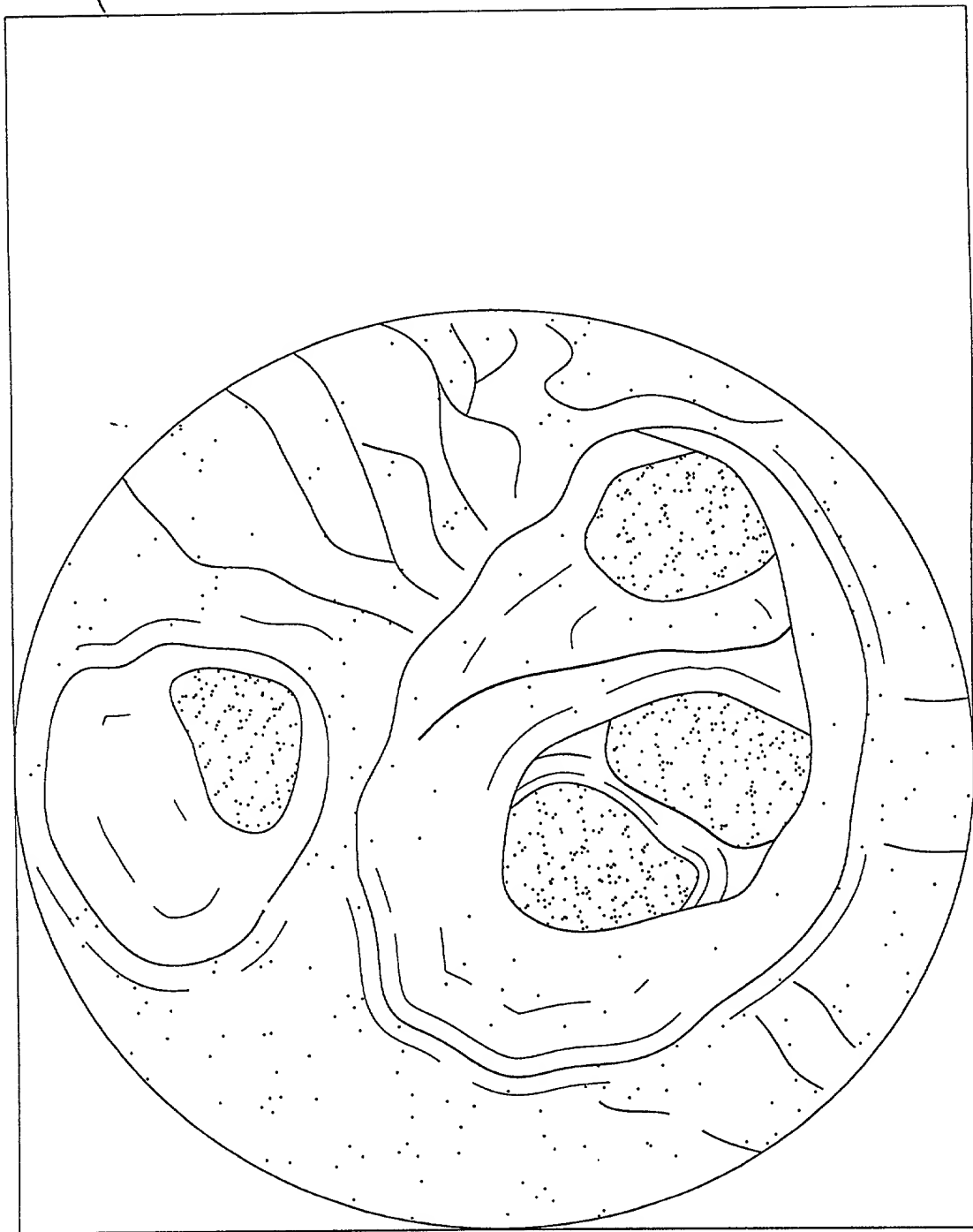
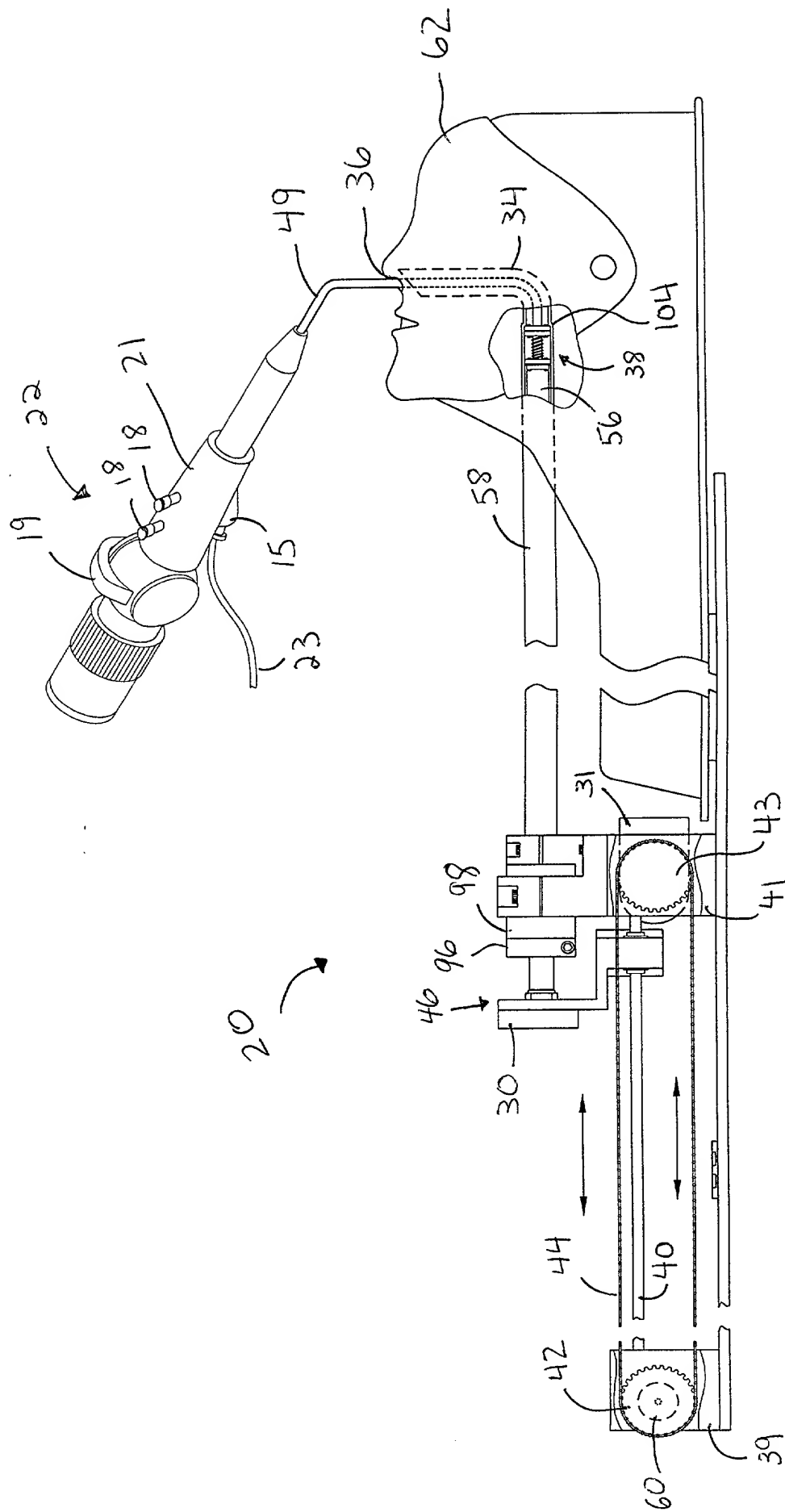
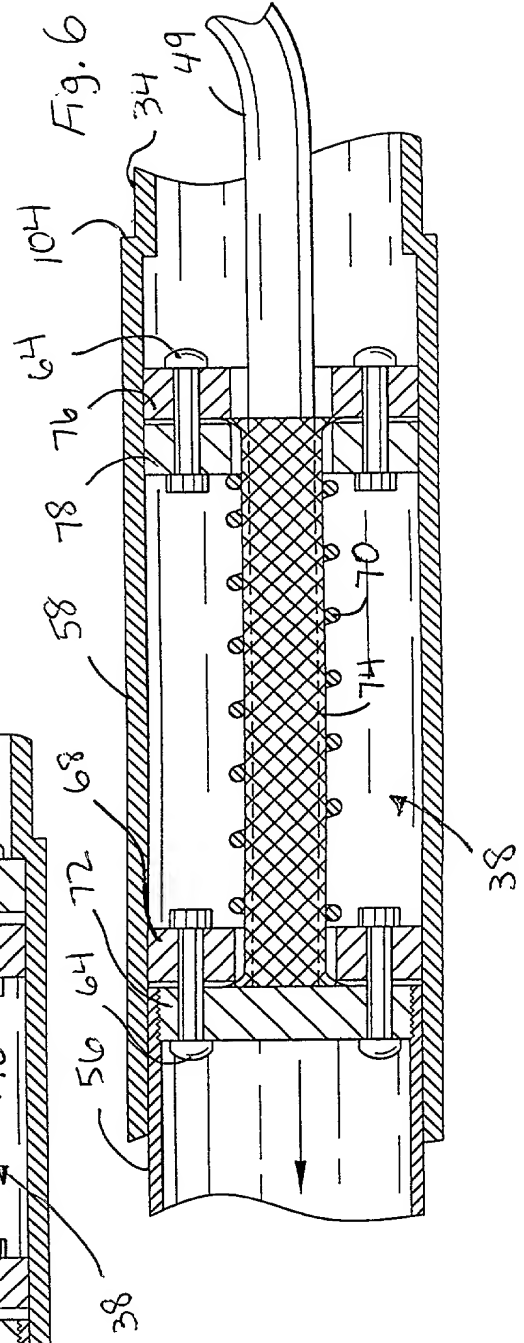
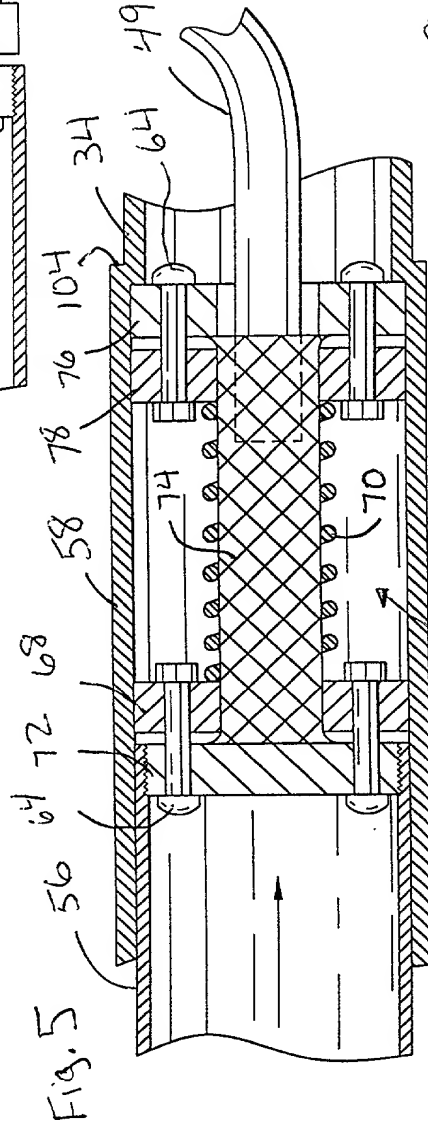
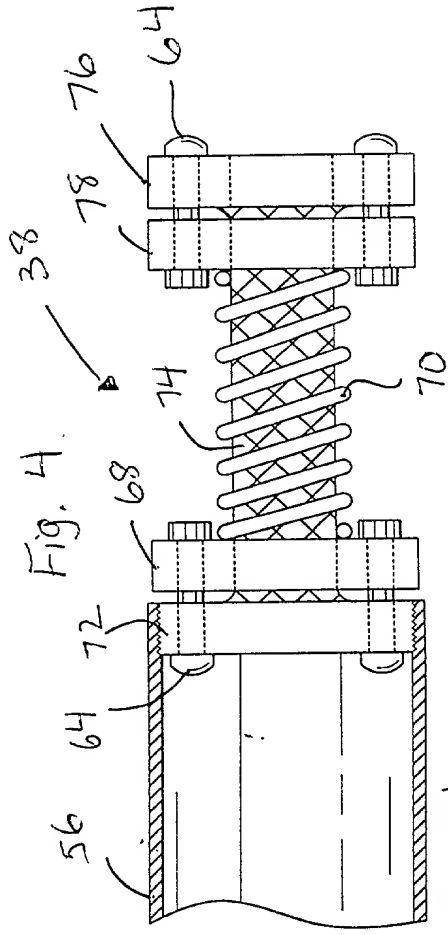


Fig. 2

~ 28





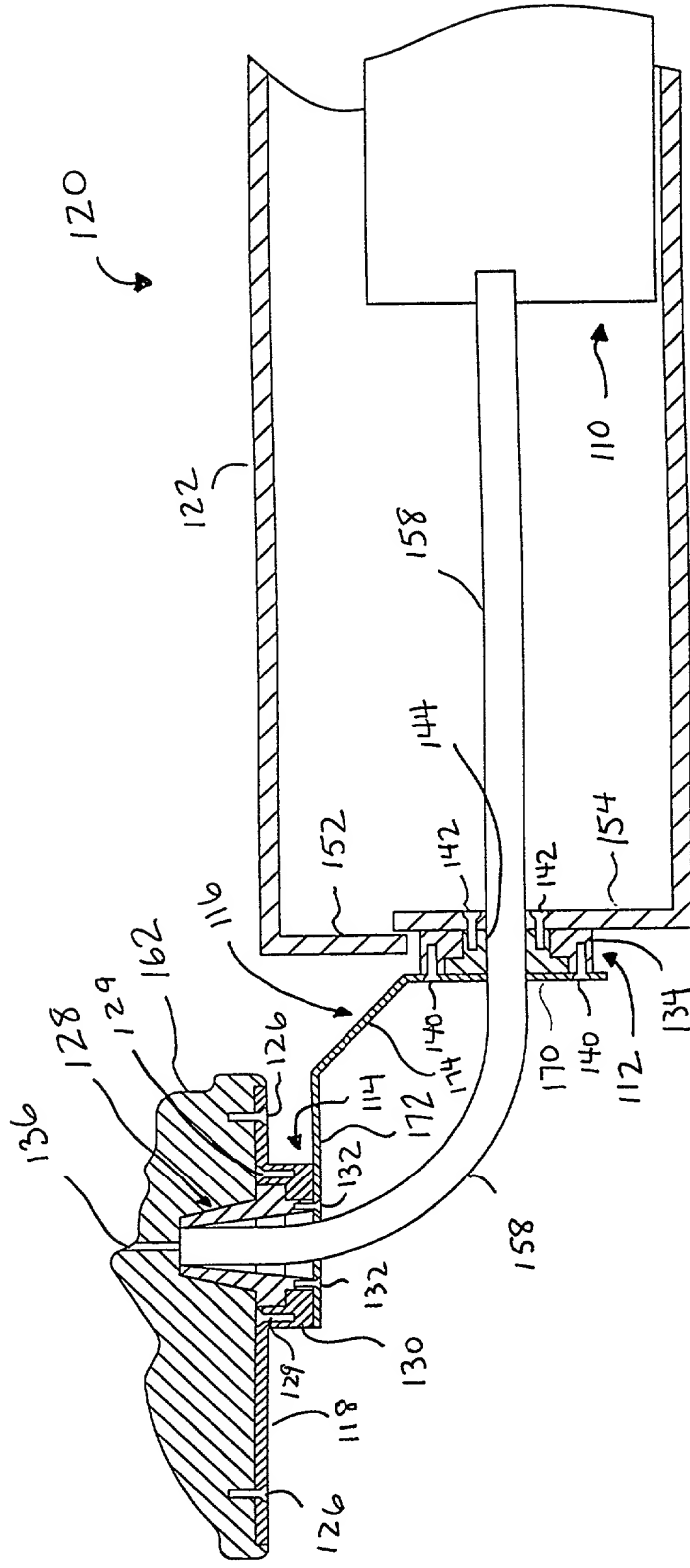


FIG. 7

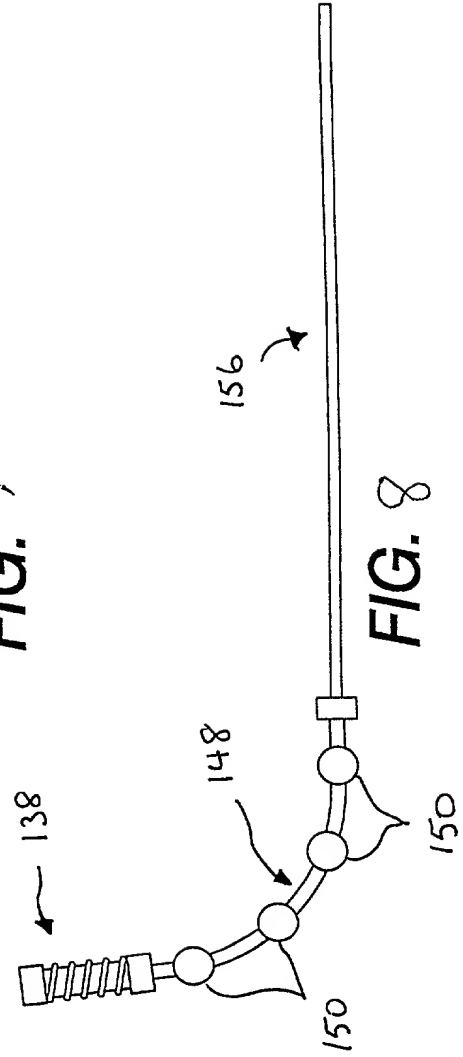
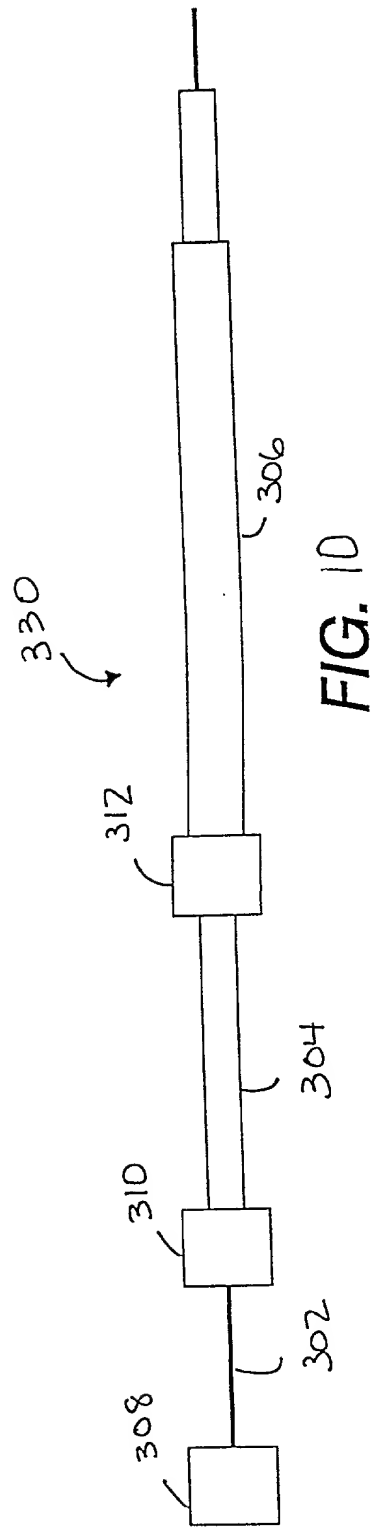
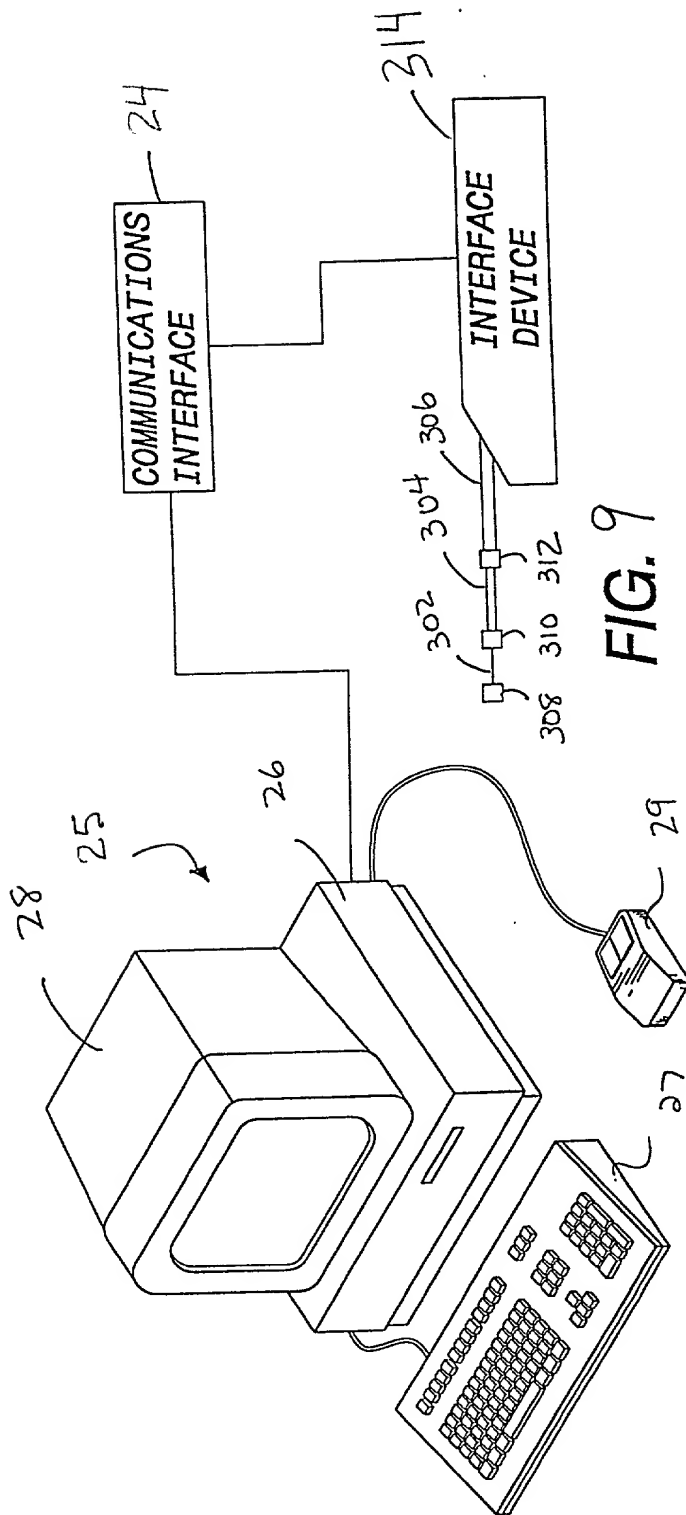
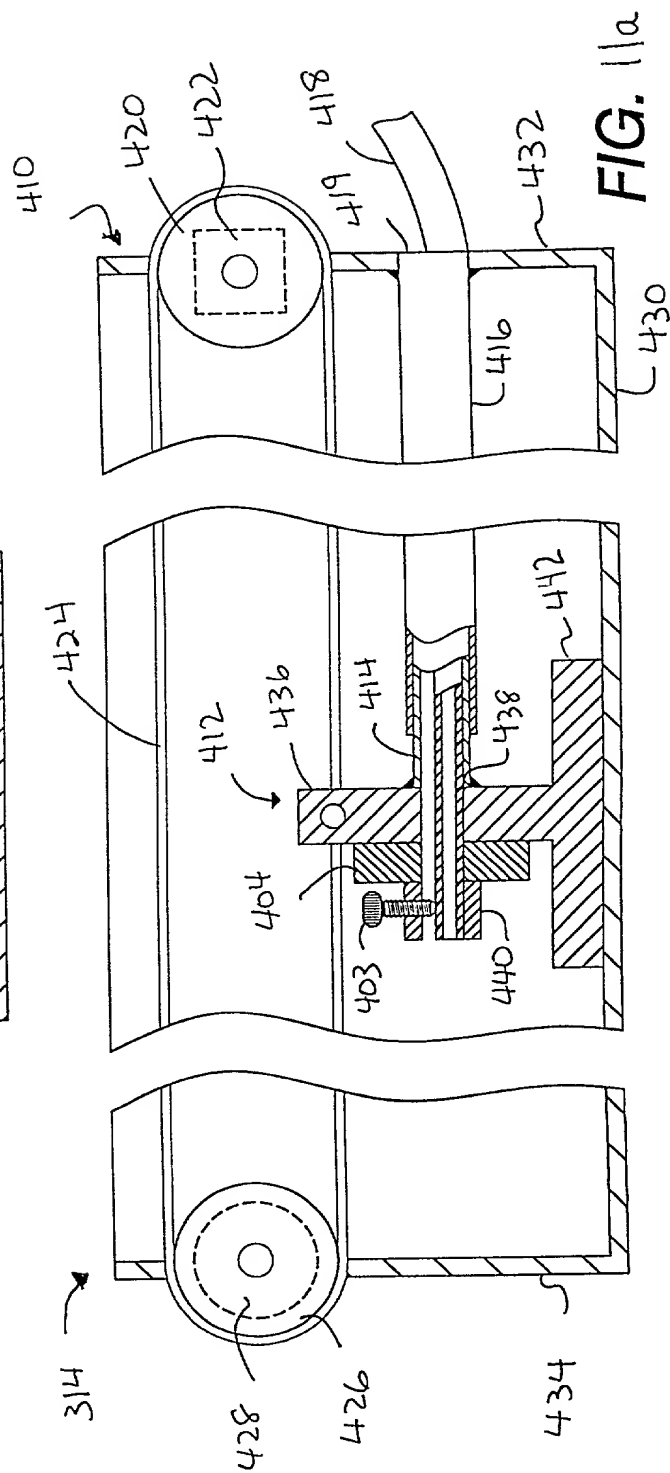
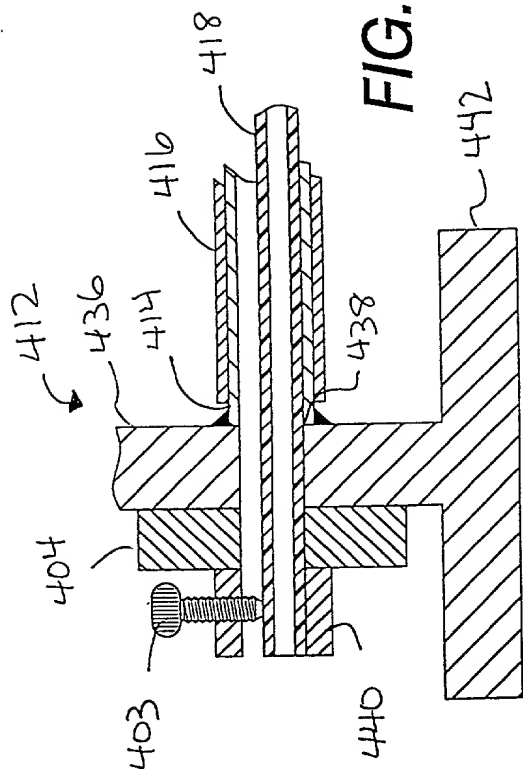


FIG. 8





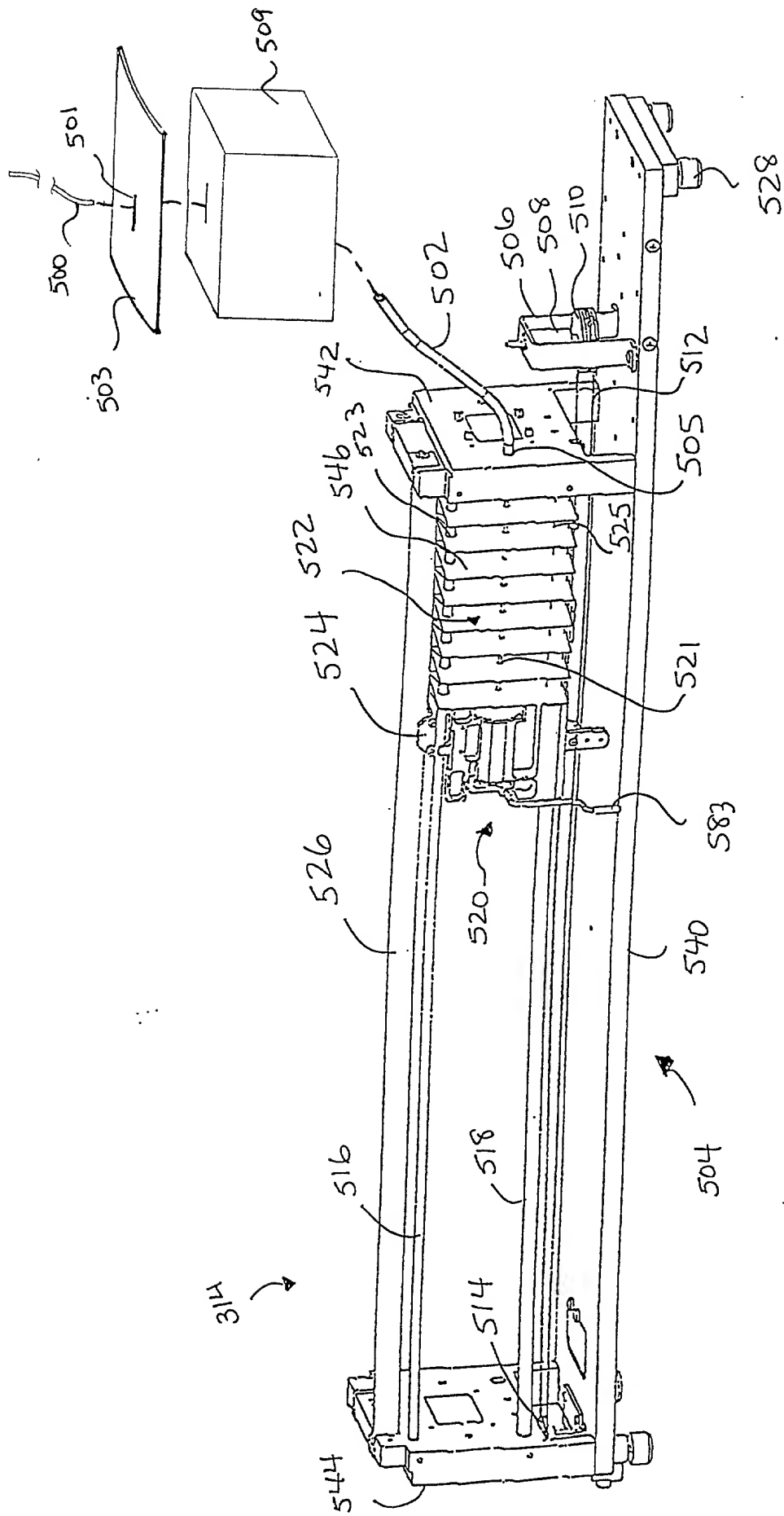


Fig. 12

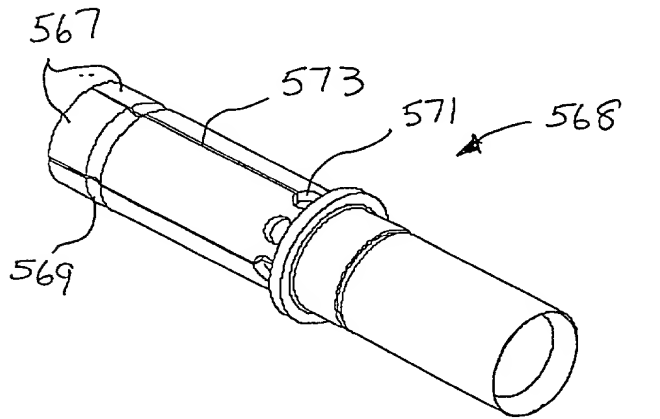
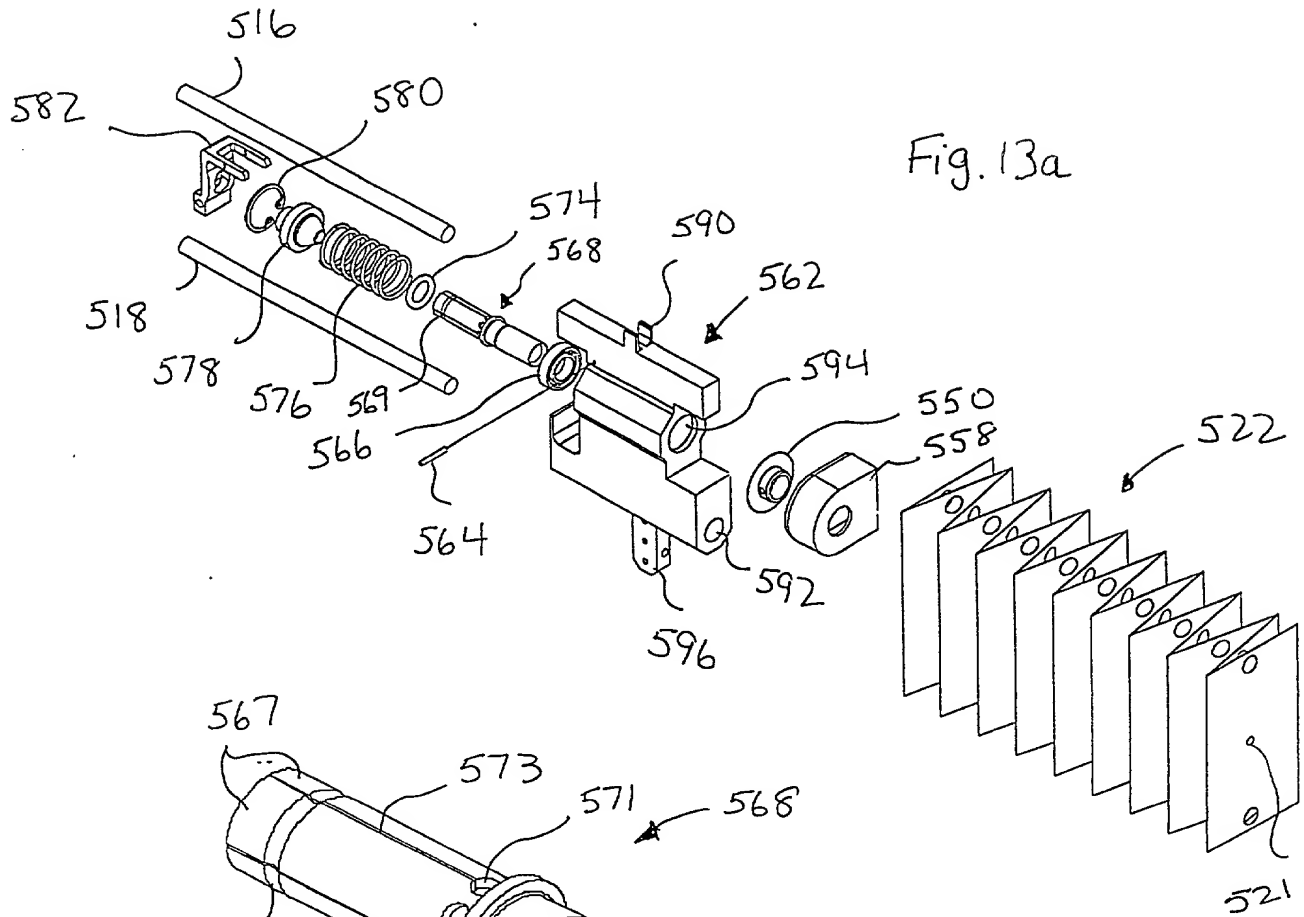


Fig. 13b

Fig. 14a

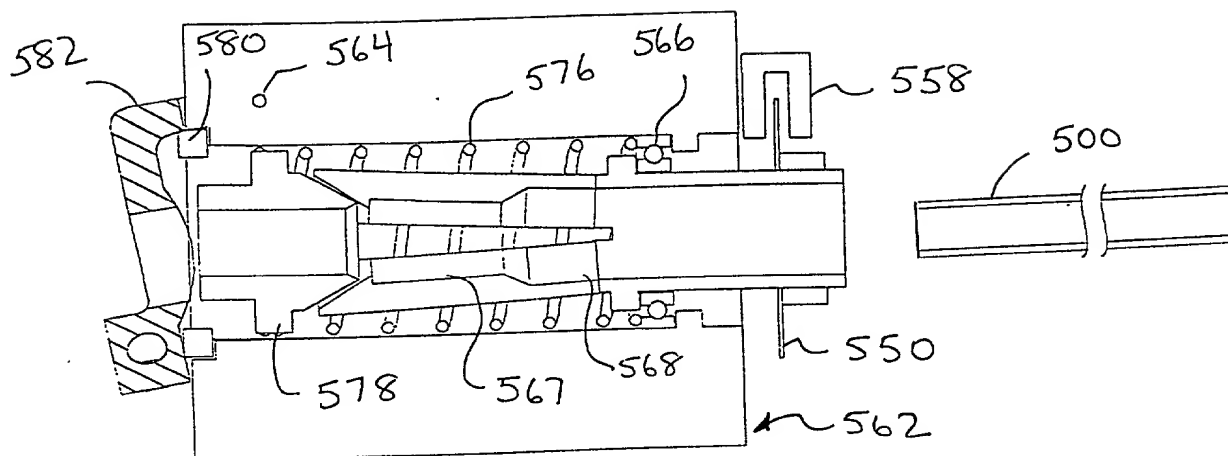


Fig. 14b

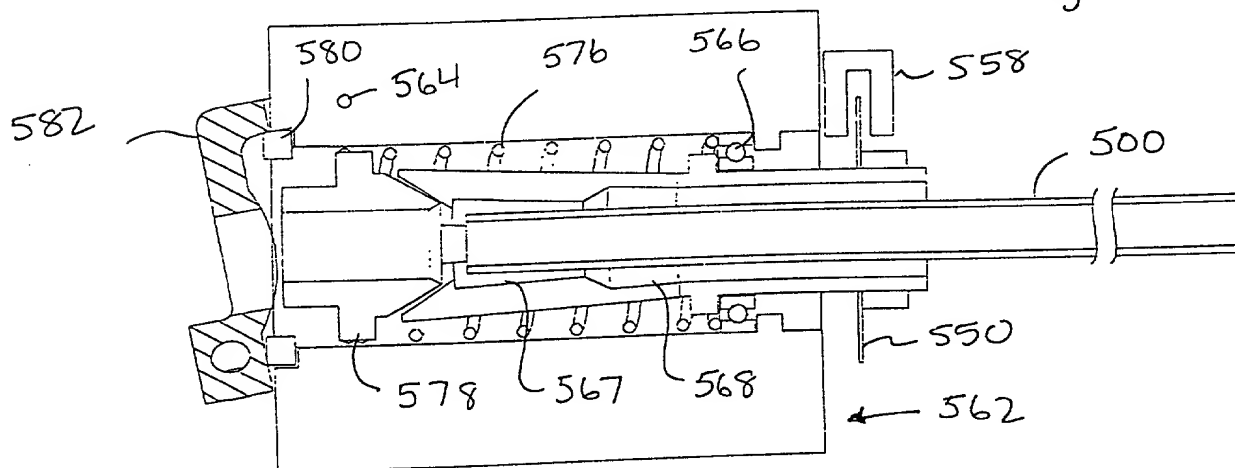
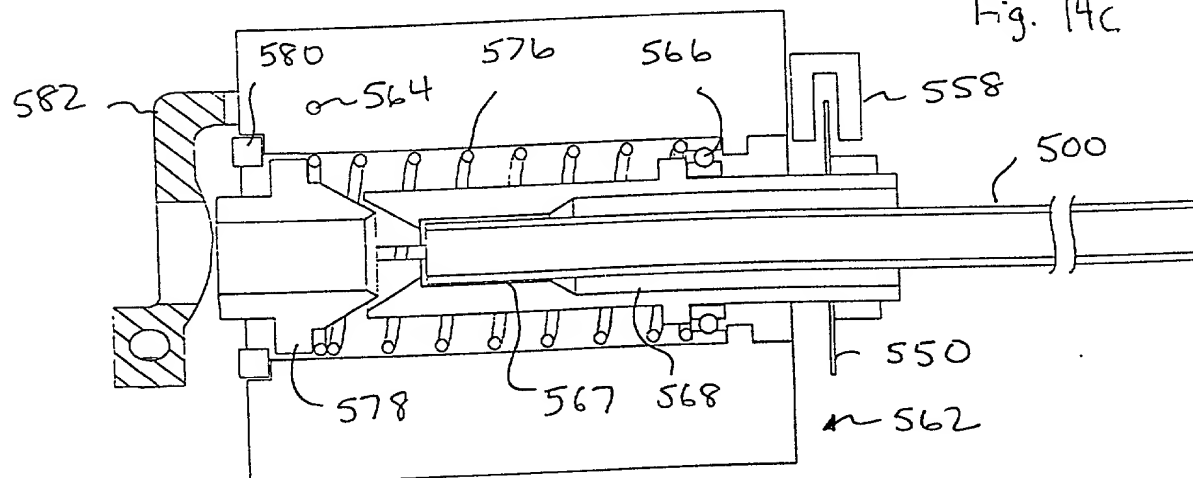


Fig. 14c



56270 69672250

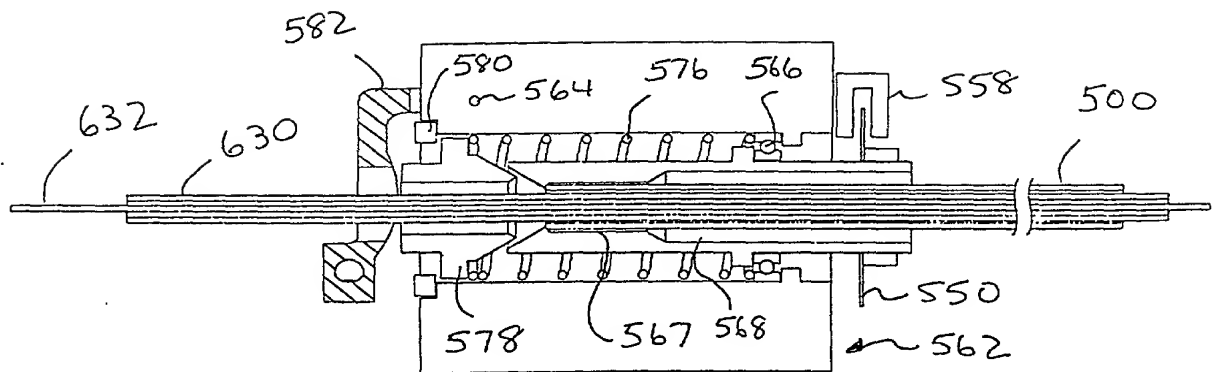


Fig. 14d

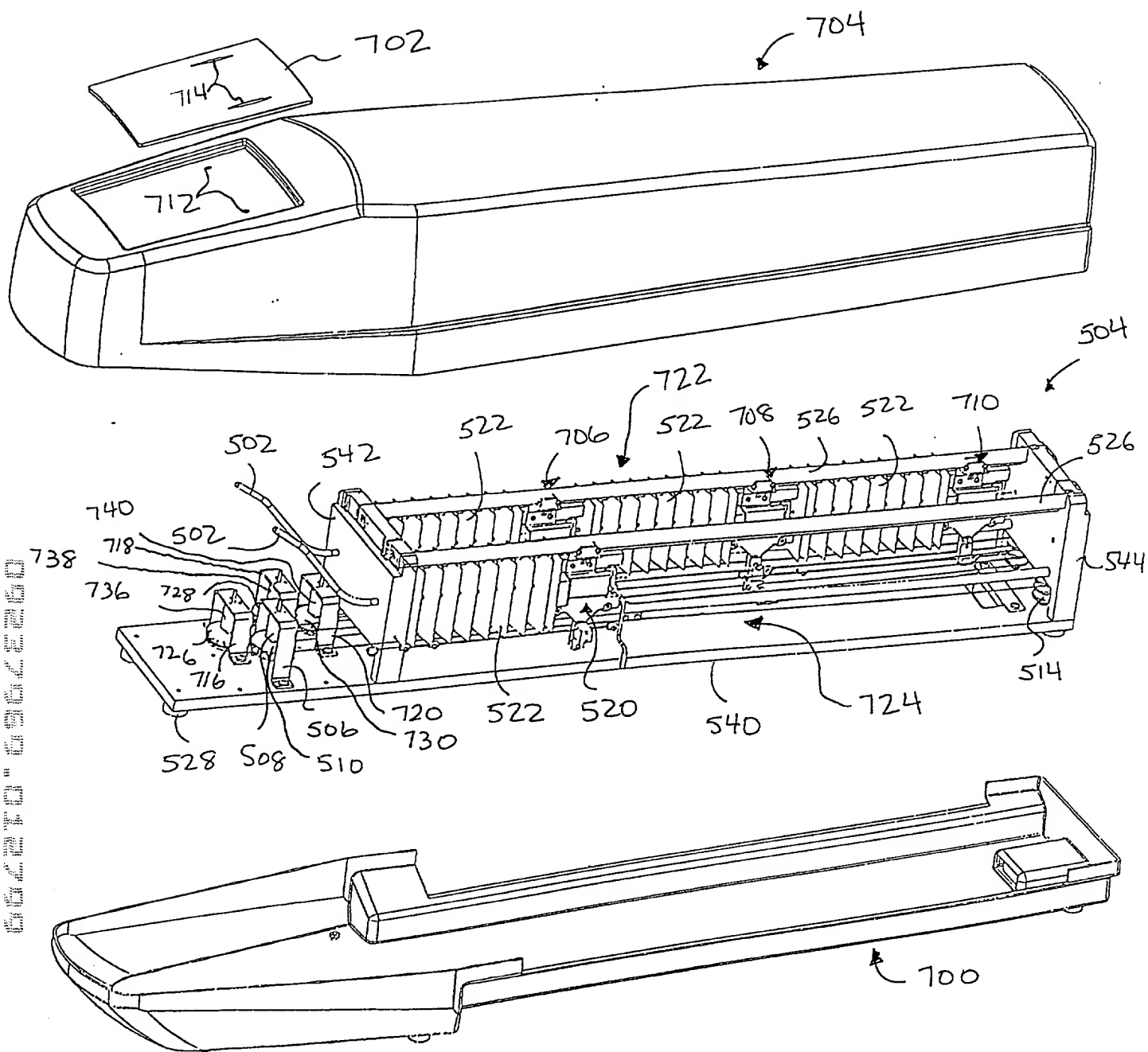


Fig. 15

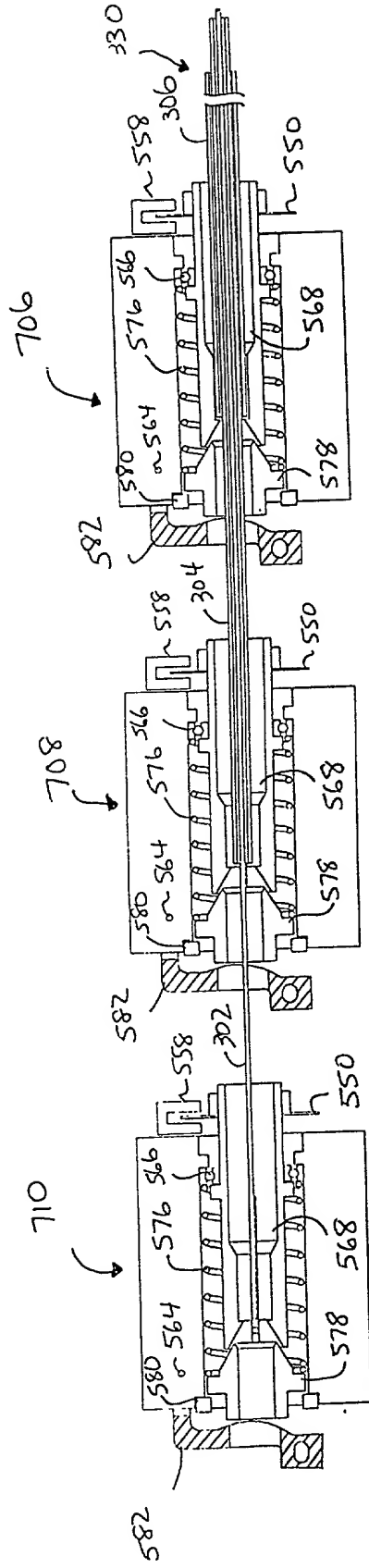


Fig. 16

Fig. 17a

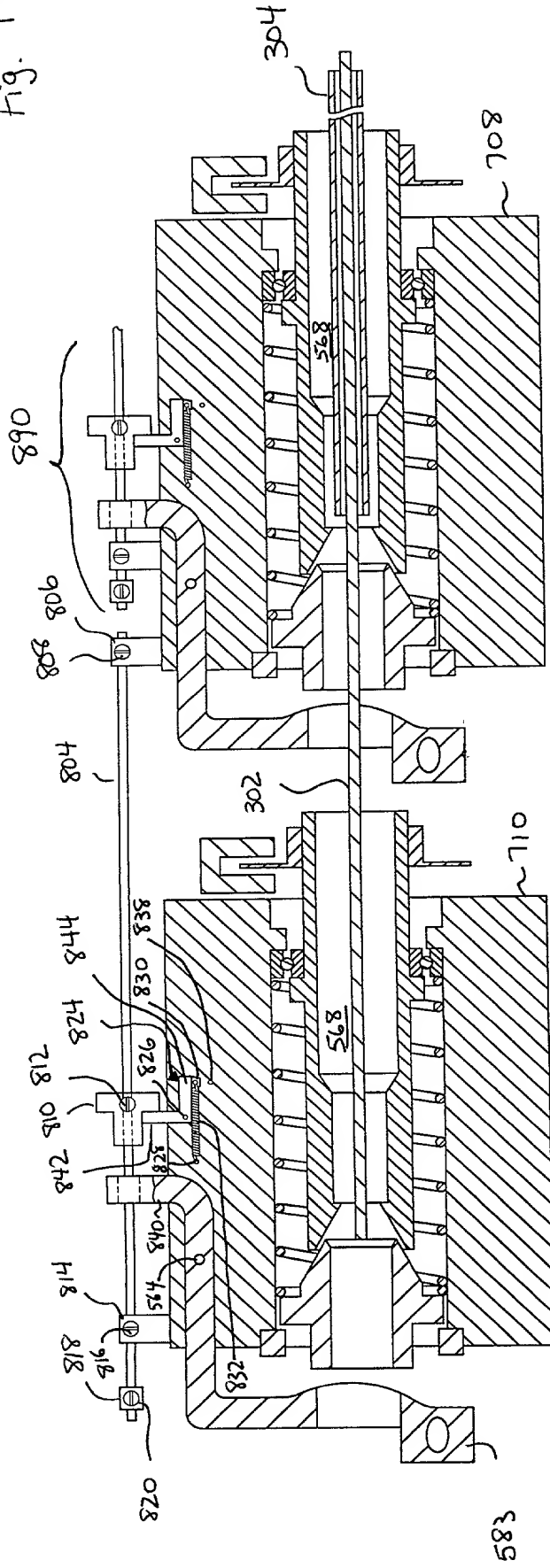


Fig. 17b

